“The Promotion & Marketing of OxyContin Twenty Years Later: an opioid crisis, lessons learned, and needed changes”

October 19, 2020

ART VAN ZEE, MD
STONE MOUNTAIN HEALTH SERVICES
ST. CHARLES CLINIC
ST. CHARLES, VIRGINIA
Financial Disclosures: none
MY DEEPEST GRATITUDE TO VANDERBILT—
FACULTY & HOUSE STAFF

• Drs. TE Brittingham, Grant Liddle, Roger DePrez, John Oates, Anderson Spickard, William Salmon, Gottlieb Friesinger, Josh Billings, William Schaffner, John Flexner, John Leonard, Allen Kaiser, John Sergent

• House staff: Frederick Billings, Seth Cooper
General overview of the talk

• The Vanderbilt Student Health Coalition & its legacy

• Personal story—how I became involved with the opioid crisis

• Brief overview of the national opioid crisis

• The Promotion & Marketing of OxyContin

• Litigation: outcomes needed for the public health

• Lessons learned & opportunities for change
Miners in St. Charles circa 1949
VANDERBILT STUDENT HEALTH COALITION

- 1969—
- WW “Bill” Dow & Dr. Amos Christie—early movers & shakers
- Health Fairs in northeast Tennessee and southwest Virginia
- > 800 students and multiple faculty members participated
- 1973---first Health Fair in St. Charles
- 1974---second Health Fair in St. Charles
- --co-directors---Nancy Raybin & Polly McClanahan

http://coalition.web.unc.edu/about/timeline-of-the-student-health-coalition
A FREE MEDICAL SERVICE FOR EVERYONE

JUNE 28 - JULY 13

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You and your neighbors are invited to the St. Charles Health Fair, June 28 to July 13 at the St. Charles School. This FAIR will be a free medical service for everyone sponsored by the Vanderbilt University Student Health Coalition of Nashville, Tennessee and the St. Charles Health Fair Committee. Doctors, nurses, medical and nursing students, and community workers will be at the FAIR. All of the services provided by the FAIR will be free of charge to everyone.

All children and adults should plan on coming to the FAIR from June 28 to July 9. Children's physical exams, blood tests, and immunizations will be given at this time. Adults will have their blood, urines, and hearts tested and their chests x-rayed. All adults will be given a return appointment between July 9 and July 13 for their physical exams.

Some treatments will be available. The doctors will discuss the results of the exam and tests with you and send a copy of the results to your regular doctor, as well as the Lee County Health Department, if you so wish. Nursing staff will remain for several weeks after the FAIR to help with adult and child follow-up.

If you need a ride to the FAIR, transportation will be available. Leave your name and directions to your home with Edith Rogers (383-4119) (call after supper).

If you have any further questions, please don't hesitate to call Nancy Raybin (383-4319) or Richard Needham (346-1901).

We hope we'll see you all at the FAIR.

St. Charles Health Fair Committee
Health Fair Reaches Many

Many Lee County Health Fair swipe cards in the week of the fair -- the Health Fair that is, and took advantage of the free medical services sponsored by the Vanderbilt University Student Health Coalition and the St. Charles Health Fair Committee. The Fair has left its mark on the health community.

The committee met again recently to finalize their charter as a non-profit organization, make committee assignments, and plan their next steps. The committee believes that the Board of Directors who will serve until new elections in December 1973, will bring renewed energy to the Health Council.

The committee elected President and Nell Stewart was elected Secretary-Treasurer. The following people are members of the Board: Charlie Provine, Eunice Layne, Rev. Eugene Huff, Edna Fisher, Mary Kirk, Howard Elliott, Jim Dean, Curtis Ricker, Lucy Henigan, James Hobbs, C. F. Gilkes, Beth Davids, Lily Mooneyham, Franch Cooper, Rev. Kenneth Ellis, Janie Holman and Nell Stewart.

The St. Charles Health Council will meet again on August 9, 1973 at 7:30 in the School Lounchroom. The entire community is urged to attend. The charter will be presented and the other committee assignments will be announced. The Fund-raising Committee is presently planning ways to raise necessary funds and your suggestions will be appreciated. A building has been acquired in St. Charles which will serve as the temporary office and future

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Local fund raising

Quilts, cake walks, Fried chicken dinners, Door to door, car washes, Theater.....and more fried Chicken, beans, and Corn bread
These and many other people of the St. Charles area are working constantly toward the day when a clinic will be built on this site. The land has been purchased and much has been accomplished.

Rummage sales and numerous other ways of raising funds are planned and carried out by the St. Charles Health Council, a non-profit corporation formed to promote and complete the clinic.
Province Honored By St. Charles Health Council

Charles Province of Pennington Gap, was honored in a most surprising manner last Sunday night. Having been literally been sought to the Pennington High School cafeteria, he was asked to walk into a crowd of 200 friends who were

Clinic Fund Raising Effort Nets $1100

The current effort now underway by the Western Lee County Health Clinic, Inc., to raise funds for a clinic building is now underway and going strong.

This endeavor, like the one at St. Charles, started with the health fairs. These events brought the urgent need for such clinics to the attention of the people of both areas in a most dramatic manner. Free physical examinations were offered to the people of these areas and the findings of the examinations convinced the people of these two areas of Lee County that certain medical services were urgently needed in their immediate areas.

St. Charles now has a building, some equipment and a limited amount of personnel. It is the hope of the people of this area that the clinic will soon be staffed with a doctor and a nurse practitioner.

Local effort in raising funds has far surpassed what was anticipated.

Now the same effort is underway in the western area...
CLINIC PLANS DISCUSSED — A group of officials of the St. Charles Health Council discuss plans for the future at a recent meeting. Seated, left to right, are Howard Elliot, Nancy Raybin, Charlie Provence and Curtis Ricker; standing, left to right, are Ezra F. Cooper and Janie Holman.

St. Charles Area Seeks Medical Unit

By GEORGE DALTON
H.C. Correspondent
ST. CHARLES, Va. — The first meeting was held this week to discuss forming a medical unit to provide long-range solutions to health problems. More than 60 residents attended the meeting to discuss their medical needs and long-range solutions to problems.

A chairman, secretary and committee of representatives from the area were formed to lead and direct the St. Charles Health Council.
Before and After these pictures illustrate the St. Charles Health Clinic in action. The clinic is being held in cooperation with Cia, who discussed its programme and services in detail.

The St. Charles Health Clinic
A Vision Of Hope
The recently completed clinic building is a source of real pride for the people of the St. Charles area. Their next goal is equipment and personnel for the building.

St. Charles Takes Pride In Recent Accomplishments

At one time St. Charles and the surrounding coal camps was where the action was in Lee County. All that changed when the coal business almost died and folks had to move away to find other employment. The tough times lasted eraically wiped from the face of the earth. In some places it is almost impossible to tell were they stood. St. Charles, for a while, looked as if it might be doomed to the same fate. But things are changing now and for the better! The

Perhaps the entire change can be credited to the booming coal business. This thing industry has, no doubt, played a part in the tradition that is now taking place in the area. High wages and employment for those who
Pictured above is the clinic building presently being constructed in St. Charles. The 76 ft. x 30 ft. building will house 12 rooms, plus facilities for waiting rooms, according to Curtis Ricker, Chairman of the Finance Committee. Ruth Ricker, Aileen Shepherd and Howard Heron are also included in fund raising. Sam and Burl Hughes are the carpenters in charge of construction.
The St. Charles Health Council, a Virginia grassroots self-organized group, constructed this new health clinic with initial help from the Campaign for Human Development, and the facilitation of Sister Beth Davies, CND.
20th Anniversary—St Charles Community Health Clinic 1996

Reminiscing

Former and present members of the board of directors of the St. Charles Health Council recently at the St. Charles Community Health Clinic to reminisce about the council and the growth of the original idea of building a clinic in the town. Pictured, left to right, are: Janie Holman, Nell Swartz, Tony Lawson (clinic executive director), Edna Tabor, Rochester Woodard (board president), Charlie Province, Sister Beth Davies, and Louise Wade.

St. Charles Health Council
To Celebrate Anniversary

The St. Charles Community Health Council will hold its 20th anniversary this year. The celebration will be held on October 1, 1996.
Stone Mountain Health Services 2019
-- a Federally funded Community Health Center--

- 11 medical clinics in 7 counties southwest VA
- One dental clinic site—one dentist
- 17 primary care providers—6 MDs & 11 mid-levels
- 2 Black Lung & respiratory care centers
- 2019: 17,183 patients; 65,709 clinic visits
- Behavioral Health: 6 clinical psychologists,
  2 LCSW, 1 MSW
How I became involved in the problem
GENERAL OUTLINES OF OUR BUPRENOPHINE TREATMENT PROGRAM
Buprenorphine treatment --- case study

• “TJ” – 42 yowm, Harlan County, hard working construction worker, opioid use disorder with OxyContin, IVDA & had Hepatitis C
• Entered into our buprenorphine treatment program early 2003
• Didn’t do well, returned to using, dropped out of treatment program
• Re-entered treatment program 3 months later
• Few lapses the next few months---then able to stop
• Abstinent from all illicit drug use since 12/31/2003
• Has been working in the coal mines the last ten years
• Has been able to be a good, responsible, & very involved father and husband
• By himself, built a house for his family
• Remains in treatment on bup/naloxone 12 mgm daily
The Prescription Opioid Crisis is brought to us by the Medical Profession & the Pharmaceutical Industry.
The Opioid Epidemic

- 1999 to 2010: Quadrupling of prescribed opioids
- 1997 to 2011: 900% increase in people seeking treatment for opioid use disorder
- Since 1999, almost 400,000 people have died of opioid overdoses
- From 2002 through 2011, 80% of people who use Heroin reported use began with Rx opioids

Learner AM. Opioid Injection in Rural Areas of the United States. JAMA, September 17, 2019
Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, United States, 1999–2010

[Graph showing trends in opioid sales, deaths, and treatment admissions from 1999 to 2010.]

Evolution of Drivers of Overdose Deaths:

- Analgesics
- Heroin
- Fentanyl
- Stimulants

Data from CDC WONDER Database

Compton WM & Jones CM, Ann NY Acad Sci, 2019
Physician Prescribing & Misprescribing

- Legitimate physicians influenced by the changing narrative on pain management and by the influence of the pharmaceutical industry

- The worst of marketplace medicine—pill mills
FLO RIDA

-- center of nation’s RX opioid problem
-- “pill mills” & lax prescribing
-- marketplace medicine at its worst
-- Broward County 2009: all 50 of the top oxycodone prescribing doctors in the nation were in Florida, 33 in Broward County alone
-- Broward Co.—more pain clinics than McDonald’s & Walmarts combined
-- Broward Co.—in 2007—4 pain clinics
-- in 2009 115 pain clinics
Florida Pain Clinic---advertisement

- Chronic Pain
- Detox
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- Stop Smoking
- Auto Accidents

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PHARMACEUTICAL INDUSTRY MARKETING

Focus on Purdue Pharma Marketing & Promotion of OxyContin
I focus on issues surrounding the promotion and marketing of controlled drugs and their regulatory oversight. Compared with noncontrolled drugs, controlled drugs, with their potential for abuse and diversion, pose different pub-

Stamford, CT), a sustained-release oxycodone preparation, illustrates some of the key issues. When Purdue Pharma introduced OxyContin in 1996, it was aggressively marketed and highly promoted. Sales grew from $48 million in double-blind studies comparing OxyContin given every 12 hours with immediate-release oxycodone given 4 times daily showed comparable efficacy and safety for use with chronic back pain⁴ and cancer-related pain.⁵,⁶ Randomized array of approaches to promote OxyContin.

PROMOTION OF OXYCONTIN

From 1996 to 2001

The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy

Art Van Zee, MD
OxyContin Beach Hats—for physicians
“SWING IS ALIVE”

“Swing in the right direction with OxyContin”

CD music swing tunes—for physicians
• OxyContin was not a “miracle” drug

• Oxycodone offered no advantage over other potent opioids

• OxyContin was comparable to short acting oxycodone

• OxyContin was comparable to CR morphine in efficacy & safety
IR oxycodone vs CR oxycodone

Comparable
Efficacy & Safety

Hale Clin J Pain ’99 BACK PAIN
Kaplan J Clin Oncol ’98 CANCER
Stambaugh J Clin Pharm ’01 CANCER
Summary of safety

“The best conclusion is that the efficacy of the CR (oxycodone) is equivalent to the IR, with an adverse profile that is as good as the IR. I would not allow a ‘better’ claim.”

--Curtis Wright, MRO
OxyContin NDA (cont)

Summary of efficacy

“CR oxycodone appears to be a BID alternative to conventional QID oxycodone. Approval is recommended. Care should be taken to limit competitive promotion. This product….has not been shown to have a significant advantage beyond reduction in frequency of dosing.”

--Curtis Wright, MRO
OxyContin Marketing & Promotion was the most heavily financed, extensive opioid marketing campaign in the history of the industry.

$200 million in 2001
General narrative of the marketing campaign

- There is an epidemic of untreated pain in the country
- Trivialized the risks ("addiction is rare.....")
- Oversold the benefits
- Opioids can be very effective for chronic non-cancer pain (80+ percent of the opioid market)
“CME” events

• 1996-2001, Purdue conducted 40 national pain-management & speaker-training conferences. More than 5,000 physicians, pharmacists, nurses attended these all-expenses-paid symposia, where they were recruited & trained for Purdue’s national speaker bureau.

• 1996-2002, Purdue funded more than 20,000 pain-related educational programs.

• High potential for blurring marketing & education

• These types of events have been shown to influence physician prescribing

Wazana A. “Physicians & the Pharmaceutical Industry: is a gift ever just a gift?” JAMA. January 19, 2000
Use of sales reps to influence Physician Prescribing

- Use of sophisticated marketing data, physician profiling, targeting the high prescribing physicians, coupled with lucrative incentives for the sales reps
- From 1996 to 2000, Purdue increased sales force from 318 to 671 & physician call list from about 40,000 to 80,000 physicians
- In 2001, average sale rep salary $55K, annual bonuses averaged $71K with bonus range from $15K to nearly $240K
- In the first quarter of 2011, 639 Purdue reps nationwide made 173,647 physician visits
- In 2013, McKinsey (consultant to Purdue) recommends intensifying concentration on the highest prescribers---who prescribe 25 times more than the low prescribers---& their data showed that that increased prescribing even more
- (continued)
Purdue had a “Core” list & “SuperCore” list of the largest prescribers in Massachusetts--& reps were ordered by management to concentrate on them----even though the reps had told management some of these were “dangerous” doctors/prescribers. Two of the “SuperCore” doctors were visited 195 times by sales reps before they lost their licenses & were sent to prison.
• Sales reps and physician prescribing (cont.)

• The top OxyContin prescriber in Massachusetts from 2008 to 2012—prescribed > 347,000 OxyContin tablets (including 200,000 of the 80 mgm); was made a speaker on the Purdue speakers’ bureau—until he lost his license in 2012

• “In Massachusetts, Purdue identified ‘high value doctors’ and managers ordered the reps to keep promoting drugs to them even after reps warned Purdue that the doctors were involved in diversion & abuse…”

Massachusetts AGO Amended Complaint---pages 40-41, page 146
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**Purdue Sales Rep Visits to One Massachusetts Doctor**
“SALES & ROYALTIES FOR PROPRIETARY DATA OF THIS SORT PROVIDE MORE THAN TWICE THE REVENUE COLLECTED THROUGH MEMBERSHIP DUES”


Mike Magee, MD. “Code Blue: Inside America’s Medical Industrial Complex” p. 14
Trivializing, Misrepresenting the risk of Addiction

- Promotional literature and audiotapes for physicians
- Brochures & videotapes for patients
- Through its “Partners Against Pain” website
- Claimed that the risk of addiction from OxyContin was extremely small
- Purdue trained its sales force to carry the message that the risk of addiction was “less than one percent”

“While opioids can be abused and may be habit forming, clinical experience shows that ‘addiction’ to opioids legitimately used in the management of pain is very rare……in trials in almost 25,000 patients with no history of drug dependence, there were only 7 case of iatrogenic drug addition.” Partners Against Pain—“Professional Education” module, circa 2000
In 2007, in the Federal Court House in Abingdon, Virginia, Purdue pled guilty to criminal charges of misbranding OxyContin by claiming it was less addictive and less subject to abuse and diversion than other opioids, and paid $634 million in fines.
The Porter and Jick ‘Study’ – a letter to the NEJM Jan 10, 1980

Reported that of 11,882 patients who received at least one narcotic preparation while hospitalized, there were only four cases of reasonably well documented addiction.
Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients\(^1\) who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,\(^2\) Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Jane Porter  
Hershel Jick, M.D.  
Boston Collaborative Drug Surveillance Program Boston University Medical Center, Waltham, MA 02154
Patient starter coupon program for OxyContin

- Provided patients with a free limited-time Rx for a 7-30 day supply of OxyContin
- 34,000 coupons had been redeemed nationally by 2001 when program ended
- Later followed by a “savings card”
  -- in 2009, more than 160,000 patients had used the opioid savings card
Savings cards are effective in keeping patients on OxyContin

More New Patients Remain on Therapy After 90 Days When a Savings Card Is Redeemed

Purdue internal strategy presentation from 2011

Massachusetts AGO—Amended Complaint--2019
Financial ties between the Opioid Industry & Third Party Advocacy Groups

- Purdue Pharma, Janssen Pharmaceuticals, Mylan N.V., Depomed, Inc, and Insys Therapeutics gave nearly $9 million in payments to 14 outside groups working on chronic pain and other opioid-related issues between 2012 and 2017.

- These groups include: American Academy of Pain Medicine, American Chronic Pain Association, American Pain Foundation, The National Pain Foundation, American Pain Society, among others.

- “Initiatives from the groups in this report often echoed and amplified messages favorable to increased opioid use----and ultimately, the financial interests of opioid manufacturers.”

Fueling an Epidemic: Exposing the Financial Ties between Opioid Manufacturers and Thirty Party Advocacy Groups. -U.S. Senate Homeland Security & Governmental Affairs Committee
Purdue extensively promoted opioids for chronic non-cancer pain

--VERY LIMITED EVIDENCE ON THE EFFICACY FOR CHRONIC PAIN
--VERY CLEARLY THE RISKS ARE HIGHER

Purdue promoted extensively for a more liberal use of opioids--to primary care docs who often have less training in pain & addiction issues than some other specialties
Original Investigation | Substance Use and Addiction

Association of Pharmaceutical Industry Marketing of Opioid Products With Mortality From Opioid-Related Overdoses

Scott E. Hadland, MD, MPH, MS; Ariadne Rivera-Aguirre, MPP; Brandon D. L. Marshall, PhD; Magdalena Cerdá, DrPH, MPH

Abstract

IMPORTANCE Prescription opioids are involved in 40% of all deaths from opioid overdose in the United States and are commonly the first opioids encountered by individuals with opioid use disorder. It is unclear whether the pharmaceutical industry marketing of opioids to physicians is associated with mortality from overdoses.

OBJECTIVE To identify the association between direct-to-physician marketing of opioid products by pharmaceutical companies and mortality from prescription opioid overdoses across US counties.

DESIGN, SETTING, AND PARTICIPANTS This population-based, county-level analysis of industry marketing information used data from the Centers for Medicare & Medicaid Services Open Payments database linked with data from the Centers for Disease Control and Prevention on opioid prescribing and mortality from overdoses. All US counties were included, with data on overdoses from August 1, 2014, to December 31, 2016, linked to marketing data from August 1, 2013, to December 31, 2015, using a 1-year lag. Statistical analyses were conducted between February 1 and June 1, 2018.

Key Points

Question To what extent is pharmaceutical industry marketing of opioids to physicians associated with subsequent mortality from prescription opioid overdoses?

Findings In this population-based cross-sectional study, $39.7 million of opioid marketing was targeted to 6,641 physicians across 2208 US counties between August 1, 2013, and December 31, 2015. Increased county-level opioid marketing was associated with elevated overdose mortality 1 year later, an association mediated by opioid

JAMA, January 18, 2019
“Conclusions and Relevance: In this study, across U.S. Counties, marketing of opioid products to physicians was associated with increased opioid prescribing and, subsequently, with elevated mortality from overdoses. Amid a national opioid crisis, re-examining the influence of the pharmaceutical industry may be warranted.”
• Bureau of Economic Research –November, 2019
“ORIGINS OF THE OPIOID CRISIS AND ITS ENDURING IMPACT”

• Purdue marketed much less in state-based triplicate prescription programs

• OxyContin distribution was 50% lower in “triplicate states”

• “While triplicate states had higher rates of overdose deaths prior to 1996, this relationship flipped shortly after the launch and triplicate states saw substantially slower growth in overdose deaths, continuing even twenty years after OxyContin’s introduction.”
Figure 2: Drug Overdose Death Rates By Triplicate State Status

A: All Drug Overdose Deaths  B: Opioid Overdose Deaths

Notes: We use geocoded NVSS data to construct total overdose and opioid overdose deaths per 100,000. See Section 3.1 for codes used in each period. The vertical line marks the introduction of OxyContin in 1996.
The complex litigation---what will it bring?

Big Pharma Is Starting to Pay for the Opioid Crisis. Make Those Payments Count.
Money from Johnson & Johnson and Purdue Pharma could make a big difference — but only if it goes to the right places.
By The Editorial Board-----New York Times, August 28, 2019

• 1998 Big tobacco & 46 states agreement--$125 billion paid over 20 years

• In 2019, less than 3% nationally of the tobacco proceeds has been spent on public health matters related to tobacco use
Maura Healey, Attorney General, Massachusetts
Editorial—Washington Post, Sept. 16, 2019
Explaining why she & 24 state attorney generals are rejecting the proposed settlement by Purdue

• Lack of accountability
• Lack of justice
• Lack of transparency
What to do with the settlement monies

We need transparency & accountability----that the monies go to prevention and treatment & aren’t siphoned off for other needs
Personal conclusions:

• That the marketing of opioids, particularly OxyContin, played a major role in igniting the country’s tragic opioid crisis.
• That whatever happens with the massive litigation with the opioid industry, we must look at the story behind the story---and make changes in regulatory oversight and the ways in which the pharmaceutical industry can market abusable & addictive drugs.
• That the most effective way to prevent a similar public health tragedy in the future would be to prohibit the marketing of any controlled drug.
• Alternative means of education for health care providers---free of pharmaceutical industry influence—must be developed for protection of the nation’s public health.
Further reading:


Pain Killer: An Empire of Deceit and the Origin of America’s Opioid Epidemic. Barry Meier. 2018

Dopesick: Dealers, Doctors, and the Drug Company that Addicted America. Beth Macy. 2018


Dreamland: the True Tale of America’s Opiate Epidemic. Sam Quinones

Death in Mud Lick: A Coal Country Fight against the Drug Companies that Delivered the Opioid Epidemic. Eric Eyre. 2020

Massachusetts AGO Amended Complaint. Unredacted. January 31, 2019
Further reading (continued)


The Opioid Epidemic: what everyone needs to know Yngvild Olsen and Joshua M. Sharfstein. 2019

Thank you!

Art Van Zee, MD
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Stone Mountain Health Services
St. Charles, Virginia

avzee@stonemtn.org