

**SANDERS
PHILLIPS
GROSSMAN**

A National Law Firm

Opioids Task Force

PRESS RELEASE

August 2017

GARDEN CITY, NEW YORK/PRNewswire/ -- Sanders Phillips Grossman, L.L.C., a national law firm, fights back against opioids manufacturers.

The United States Centers for Disease Control and Prevention estimated that the abuse of powerful prescription painkillers, opioids, costs the economy over \$78.5 billion dollars annually and growing. Billions in problems require social injustice law firms to fight back against manufacturer enablers, seeking solutions.

Sanders Phillips Grossman, formed a special task force to seek justice for local and State municipalities for costs associated with the epidemic caused by the pharmaceutical industry with attorneys and former government officials dedicated to fighting against this injustice.

Marc D. Grossman, Esq., the Senior Managing Partner heads the task force. Mr. Grossman has been an advocate for consumer rights for over twenty-five years, He has served on numerous committees on the Federal and State levels. He is known as one of the premier lawyers in the country receiving awards and accolades for his efforts.

The task force includes the former Governor of Puerto Rico, Alejandro Garcia Padilla, who encountered and tried to tackle the issues of pain medication addiction in Puerto Rico. Puerto Rico is on the list of territories recommended to be put into a state of emergency by President Trump.

Melissa Sims, Esq., an attorney who has a history of fighting for municipality rights all over the nation is also a task force member. Ms. Sims is at the forefront of litigation to recover monies wrongfully spent by local State municipalities because of big drug companies valuing profits over addiction. She has also represented large unions and corporations for recoupment of medical costs and expenses associated with pharmaceutical and medical device negligence.

Dr. John Restaino, JD., as a member contributes both his medical and legal knowledge. He is a surgeon who became an attorney to advocate for patient rights against pharmaceutical and medical device companies. Through his medical and legal practices over several decades, Dr. Restaino saw first-hand the damages inflicted from poor warnings, harmful products that caused catastrophic injuries including death and the plight that addiction causes so many Americans today.

Additionally, the task force will include Randi A. Kassan and Vicki Maniatis, partners at Sanders Phillips Grossman, LLC and Senior Associate Timothy Clark who are all dedicated to fighting this injustice and will bring their extensive experience and vast knowledge and experience to the cause. Collectively, the Sanders Phillips Grossman task force will fight for justice and raise awareness about this national emergency. This follows in the firm's history as lead counsel in *In Re Oxycontin II* in the New York State litigation, representing several hundred drug addicts. Sanders Phillips Grossman, LLC also participated in several successful litigations for municipalities and unions for reimbursement of costs associated with pharmaceutical wrongful advertising and other abuses.

Sanders Phillips Grossman, LLC partners have a fifty-four year history as a leading force in social injustice litigation including mass-tort litigation and is prepared to help victims nationwide who have been harmed at the hands of the world's largest pharmaceutical and medical device manufacturer companies. Leading the charge, the Sanders Firm team is consistently investigating links and developments in mass-tort litigation at the highest level. The firm's advocates sit on the Plaintiffs' steering committees of the most widely litigated pharmaceutical claims. The firm's members continue to lead the discussion at national conventions such as Mass Torts Made Perfect, and serve as chairmen of the reputable Mass Tort Medical School, among many other notable achievements.

For questions, comments and inquiries please call 833-SANDERS or e-mail Senior Partner Marc D. Grossman at mgrossman@spglawfirm.com. Sanders Phillips Grossman, LLC has offices located

throughout the United States including New York, California, Washington, New Jersey, Illinois, Colorado and Puerto Rico. Our attorneys are admitted to practice law in state or federal courts in Arizona, Arkansas, California, Colorado, District of Columbia, Georgia, Kentucky, Illinois, Indiana, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New York, New Jersey, North Dakota, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Washington and Wisconsin. The firm and its affiliates have over fifty attorneys and two hundred support staff dedicated to fighting for social injustices in the United States.

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Marc D. Grossman graduated from The University of Michigan in 1989. After completing Brooklyn Law School and Baruch Business School's J.D./M.B.A. program while interning at the Law Department of the United Nations, Mr. Grossman became an Associate and later a Partner in the law firm of Mergel, Tubman & Grossman in New York City. Mr. Grossman is also a Founding Partner of Sanders and Grossman P.C., and Baker Sanders Barshay Grossman Fass Muhlstock & Neuwirth, LLC, and a Senior Partner at Sanders, Sanders, Block, Woycik, Viener & Grossman, P.C. and Sanders Viener Grossman LLP.



Since beginning his law career in 1993, Mr. Grossman has focused primarily on representing large groups of plaintiffs against common defendants. After six years of practicing plaintiff's personal injury in State and Federal Courts in New York and New Jersey, Mr. Grossman founded the law firm of Sanders and Grossman, P.C. in 1999 specifically to pursue claims for medical providers. This firm, and its successors, grew dramatically under his leadership, and now represent thousands of medical providers litigating claims against insurance companies, and thousands of injury victims, and now employs over forty attorneys and one hundred and fifty support staff.

Mr. Grossman had a vision of uniting the medical profession by affording them the opportunity to litigate nominal claims that were being written off by medical providers as uncollectible and had not previously been practical for most attorneys to litigate. By coordinating Discovery, utilizing the most up-to-date case management technology, recruiting top office administrators and trial attorneys, Mr. Grossman's firm was able to greatly improve efficiencies throughout the litigation process and ultimately the viability of collecting these claims. By filing over 100,000 individual lawsuits, Mr. Grossman's firms garnered the attention of the insurance industry and the medical profession in New York eventually leading to a series of mass settlements on behalf of his clients and recoveries in the hundreds of millions of dollars. In just 2006 and 2007, Mr. Grossman's firm personally litigated, negotiated and recovered over 100 Million Dollars for his medical provider clients. The unique experience Mr. Grossman garnered as an innovator and leader in the mass settlement of medical claims and mass torts made him a leader in his field in negotiating and obtaining large recoveries.

Most recently, Mr. Grossman has represented hundreds of injured clients in lead paint litigations, asbestos litigations, mold litigations, and thousands of victims of defective drugs and products. Mr. Grossman received recognition litigating Vioxx cases in New Jersey Superior Court where he served as a liaison to the media as a member of the Vioxx PSC's Public Relations Committee, and as a liaison for the Committee to many financial institutions and governmental agencies, offering a common voice for the hundreds of attorneys handling such cases and the tens of thousands of victims they represent. These efforts and the hard work of many other relentless attorneys ultimately led Merck to agree to one of the largest Civil Settlements in American History for \$4.85 Billion. In December 2010, Marc Grossman was nominated and invited to join both The Board of Directors of the New York State Trial Lawyers Association and the Executive Committee of ATLA. Mr Grossman is also a member of the Mass Tort Trial Lawyers Association and the Leaders Forum of the American Association of Justice.

Mr. Grossman has actively litigated for other large groups of plaintiffs in the following matters: In Re: Avandia Marketing, Sales Practices And Products Liability Litigation- In Re: New York Bextra and Celebrex Product Liability Litigation in New York's Supreme Court, New York County; -Case No. 273, In Re: Bextra and Celebrex Litigation, Superior Court of New Jersey, Atlantic County; -Oxycontin Litigation in New York's Supreme Court, Richmond County; -MDL-1708, In Re Guidant Corp. Implantable Defibrillators Products Liability Litigation in Minnesota; -MDL-1699, In Re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation in California; -MDL-

1742, In Re Ortho Evra Products Liability Litigation in Ohio; -MDL-1789, In Re Fosamax Products Liability Litigation in New York; and -MDL-1804, In Re Stand 'N Seal, Products Liability Litigation where one of Mr. Grossman's firms serves on the PSC. Marc's Firm is also a court appointed member of the plaintiffs steering committee in the following mass tort litigations: In Re Avandia, In Re Chantix, In Re Zicam, In Re Zimmer Knee, In Re Fosamax, and the New Jersey State Court Coordination of Levaquin. Marc's Firm is co-lead in the NY Chantix Coordination and the New Jersey Reglan Coordination, as well as, Risperdal in California, all Transvaginal Mesh PSC, and Propecia coordination. After an \$8 million verdict in Boles v. Merck for a victim of Fosamax, along with co-counsel Paul J. Sizemore, Marc led the Trial Team in Rosenberg v. Merck which was the first bellwether New Jersey Trial in Atlantic County Superior Court.

After an \$8 million verdict in Boles v. Merck for a victim of Fosamax, along with co-counsel Paul J. Sizemore, Marc led the Trial Team in Rosenberg v. Merck which was the first bellwether New Jersey Trial in Atlantic County Superior Court.

Mr. Grossman has become well known as a speaker and host of approximately twenty educational seminars designed to educate victims, the medical community and other attorneys. Mr. Grossman has been quoted and has appeared in numerous local and national forums and in the media as a legal commentator and advocate of victims rights against the corporate greed that plagues our nation.

In January 2016, Marc Grossman received the 2015 Litigator Award a significant distinction, achieved by less than 1% of all trial attorneys. This award is considered among the top honors bestowed on trial attorneys.

Marc Grossman, ambitiously took on the challenge of co-producing his first Broadway show 'Indecent'. The play premiered in October 2015, and last Sunday June 11th at the 2017 Tony Awards, the show proved to be a complete success. 'Indecent' won Best Direction of a Play and Best lightning Design of a Play, while being nominated for Best Play as well.

Victoria Maniatis

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Victoria J. Maniatis joined the firm in 2011 concentrating on pharmaceutical and medical device mass tort cases. After graduating from The Pennsylvania State University and Hofstra University School of law, she was admitted to practice in Federal and State courts in New York and New Jersey as well as pro hac vice in many courts across the country.

Both federal and state judges have appointed Ms. Maniatis as lead counsel on various Plaintiffs' steering committees including Fosamax Femur Fracture litigation as well as the Bard, Boston Scientific, Ethicon, and American Medical Systems cases within the Transvaginal Mesh litigation. Currently, she is lead counsel in New Jersey's Propecia Multi County Litigation.



Ms. Maniatis received distinguished honors in 2013 and 2014 as a Top Attorney of the New York Metro Area and a Top Women Attorney in the New York Metro area. She is also an active member of the New Jersey Association for Justice (NJAJ), the American Association for Justice (AAJ), and the New York State Trial Lawyers Association (NYSTLA). As one of the founding members of the Mass Tort Med School's annual medical seminar for Plaintiffs' attorneys, Ms. Maniatis is also committee co-chair for the Women En Masse mass tort group.

Ms. Maniatis has been an invited moderator and lecturer on several pharmaceutical cases including, Avandia, Baycol, Ortho Evra and ReNu with MoistureLoc contact lens solution. She has written articles on pharmaceutical products and vaccines. Ms. Maniatis also has experience in Aviation and insurance matters, and enjoys serving as a volunteer adjunct professor at Hofstra Law School's E. David Woycik, Jr. Intensive Trial Techniques Program. Ms. Maniatis is an avid triathlete and lives in New Jersey with her son.

John M. Restaino

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Dr. John Restaino, with Restaino Law, LLC. located in Denver, CO., is Special Of-Counsel to the Sanders Phillips Grossman firm on several litigations including, currently, the opioid 'mass fatality crisis' litigation, transvaginal mesh and talc/ovarian cancer litigation. Dr. Restaino practiced surgery of the foot and ankle from 1980 to 1990, prescribing opioids during that time and has practiced at the law since 1991. He obtained his MPH from the Division of Epidemiology at the Johns Hopkins Bloomberg School of Public Health in 2008. Dr. Restaino is an Adjunct Associate Professor at the University of South Carolina College of Pharmacy where he is actively involved in scientific pharmacovigilance.



He has been or is the chair or co-chair of the Expert & Science Committees of numerous federal MDLs dating back to the Diet Pill MDL and is currently involved in both the medical and legal evaluation of the opioids, transvaginal mesh, the proton pump inhibitors Onglyza, Risperdal, and, through his work at the University of South Carolina, has been extensively evaluation the issue of fluoroquinolone-associated disability disorder including aortic aneurysms, aortic dissections, sudden death and cardiac valvulopathy. Dr. Restaino has been appointed as the chair of the epidemiology subcommittee within the Talcum Powder MDL.

He has assisted in the development the science and experts from across the world in many of the mass tort litigations since 1991. In addition, he has successfully defended experts under *Daubert* while successfully challenging defense experts. Dr. Restaino has been involved in multiple mass tort trials including those involving Rezulin, PPA and Vioxx.

Dr. Restaino is asked to lecture across the country at both medical and legal programs. Dr. Restaino has also been a guest lecturer at both law schools and medical schools including the University of South Carolina, Harvard and Johns Hopkins.

Dr. Restaino has published peer-reviewed medical articles in addition to legal articles and written chapters in pharmaceutical law textbooks.

Alejandro García Padilla

thesandersfirm.com/attorneys/alejandro-javier-garcia-padilla/

Alejandro Javier García Padilla, is a Puerto Rican politician and attorney who served as the 11th Governor of Puerto Rico from 2013 to 2017. Prior to this position, García Padilla held various roles in the political landscape of Puerto Rico; first as Secretary of Consumer Affairs, and then as a member of the 24th Senate of Puerto Rico and as president of the Popular Democratic Party. Locally, he is a staunch advocate for maintaining the current political status of Puerto Rico as that of an unincorporated territory of the United States with self-government, while at the national level he is allied with the Democratic Party.

As governor, García Padilla shared his legislative powers with the 25th Senate and 29th House of Representatives, both controlled by his party. Regardless of this, he was not able to persuade several members of his own party to support his proposals. This failure, in addition to his low popularity, ultimately led him to not seek re-election thus becoming the second governor in Puerto Rican history to not do so after his first term.

We hope ex-Governor Garcia Padillas' strong advocacy and expertise in consumer safety will yield great results battling corporate greed.



Douglas Sanders

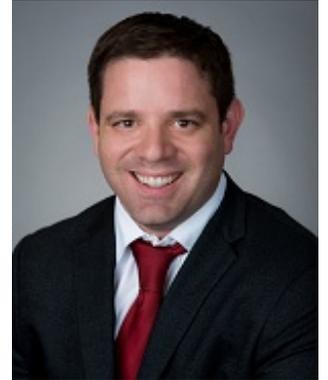
thesandersfirm.com/attorneys/douglas-sanders/

Douglas H. Sanders graduated from Duke University with honors in 1996. He attended George Washington University Law School where he graduated from in June of 2000. While in law school, Mr. Sanders interned at the Department of Justice and worked on the Oklahoma Bombing Case. He received distinguished marks for his performance there.

Thereafter, Mr. Sanders joined his family firm, Sanders, Sanders, Block, Woycik, Viener & Grossman, P.C. He handled a large body of personal injury cases. Additionally, he supervised the pleadings and motions departments and attended court conferences and conducted depositions. In 2001, he joined Sanders & Grossman, P.C. and engaged in the practice of no fault medical billing collections. Mr. Sanders became that firm's operations managing partner in charge of human resources, technology, program development and legal process.

He continued that role in Sanders, Grossman, Fass & Muhlstock, P.C. that later merged with Baker, Barshay, Neuwirth, LLP to become Baker, Sanders, Barshay, Grossman, Fass, Muhlstock & Neuwirth, LLC — now known as Baker Sanders, L.L.C. Mr. Sanders also is a member of Sanders Viener Grossman, LLP. That firm specializes in mass torts litigation. His role in that firm is to handle heavy motion work and appellate practice.

Currently, Mr. Sanders works in the Puerto Rico location with a focus on overseeing the mass torts division. He recently spoke at the 2016 Puerto Rico Investor Summit among an esteemed roster of leading legal minds, entrepreneurs, holders of political office, and world business leaders.



Randi Kassan

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Before joining Sanders Viener Grossman, L.L.P., Randi Kassan, specialized in mass claim insurance litigation for three years at Baker Sanders, L.L.C. Randi graduated from Binghamton University with a B.A. in Psychology and J.D. from Hofstra University Law School. She now specializes in Mass Tort Litigation and is well-known within the industry for her tireless effort, tenaciousness and detail-oriented work.

Randi's mass tort experience stems from specializing in New Jersey Vioxx litigation discovery, then assisting on the Avandia steering committee, as well as conducting the discovery committee during the Fosamax trial in the Superior court of New Jersey. Furthermore, Ms. Kassan has worked on the Bextra/Celebrex litigation, Oxycontin II litigation, Guidant defibrillator litigation, Zicam Cold and Remedy Litigation, Chantix litigation in Alabama and New York.



Randi is currently representing client's with injuries from prescription drugs such as Mirena, Actos, Propecia, Crestor, Reglan, Januvia, Byetta, Granuflo and defective devices such as Depuy ASR Hip, Depuy Pinnacle Hips, Stryker Hips, Bone Infuse, Biomet Hips, certain parts of the Zimmer Nexgen Knee and Transvaginal Mesh.

Randi has garnered a plethora of experience and knowledge in the mass tort community by staying intimately involved in all facets of the litigations, specifically Electronic Storage discovery, Party and Non-Party Discovery and Science in multiple mass torts across the country. She is a member of the Steering Committee in Zimmer Nexgen Knee Multi-District litigation in Illinois where she led the negotiations for developing the Case Management Order for Electronic Storage Information (ESI). She also led the negotiations for the Electronic Discovery protocol for the Propecia Multi-District Litigation (MDL) in the Eastern District of New York. Randi was appointed as a steering committee member in the In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation in the District of Massachusetts as well as the Mirena litigation in the Southern District of New York. She is a contributing member of the ESI and discovery committees in the Benicar MDL in New Jersey and Mirena Litigation in New York and New Jersey.

Randi is an active member of The Sedona Conference Working Group on electronic discovery. She is a member of the American Association of Justice. She is admitted to practice law in the States of New York, Missouri, Massachusetts, Minnesota and Washington DC. She is admitted to practice in numerous federal courts across the country including the United States District Courts in the Eastern, Western, Northern and Southern Districts of New York, Massachusetts and the District of Colorado.

Melissa K. Sims

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Melissa was born and raised in a small town in North Central Illinois. After graduating college at Illinois State University in Normal, Illinois, and while attending law school, Melissa worked as a part time employee at the Bureau County Sheriff's Department and as a legal advocate for the local domestic violence sexual assault shelter, Freedom House. She received an appointment from the Illinois Supreme Court and volunteered license to practice law while in law school prosecuting traffics and misdemeanor cases to gain experience in the courtroom.

After graduating from Northern Illinois University College of Law in DeKalb, Illinois, she joined the Wimbiscus Law Firm in Spring Valley, Illinois. She has been engaged in the general practiced of law for more than twenty years. Her representation of clients encompassed every possible facet of law: banking, hospitals, corporate, not for profit, tax, divorce, child support, probate/estate, trust, real estate, probate, civil rights, patent infringement, criminal and municipal law. She argued a precedent setting probate case before the Illinois Supreme Court.

While at Wimbiscus Law Firm, Melissa represented units of local government, including sheriffs, counties, cities, villages, school districts, zoning boards and townships. She has drafted municipal legislation and has represented units of local government in trial, appellate and federal courts.

She prosecuted hundreds of municipal ordinance violations for the towns she represented. The late William J. Wimbiscus, Jr., began practicing municipal law in 1950 and she learned from his vast experience in her municipal practice. As a tenacious municipal prosecutor, Melissa utilized a local ordinance against Exxon, CBS and Viacom for a Superfund site for one of her municipal clients. In that case, she set national precedent before the Seventh Circuit Court of Appeals on whether a non home rule unit of local government could exercise its nuisance powers during the course of a Superfund cleanup. Following this case, she represented the Village of Roxana, Illinois, against Shell and ConocoPhillips using her DePue precedent and fined the polluters for every lot, street and alley which contained benzene from the refinery. Both cases settled.

Now, Melissa maintains her own practice in Illinois, with offices in Chicago and downstate, Illinois. She represents communities nationally, helping them seek redress for public nuisance, suing her vast experience as a municipal trial lawyer. She now advises and represents municipalities and counties to seek redress against pharmaceutical corporations in the opioid crisis with Sanders, Phillips, Grossman, LLC.

She has served for ten years on the board of directors of Freedom House, also having been its President. She volunteers for local not for profits, and religious organizations. She also serves as a director on the board of a local bank.



Vince Carnevale

thesandersfirm.com/attorneys/vince-carnevale/

Vince Carnevale graduated from The University of Pittsburgh School of Law in 2001. After law school Vince worked as an Investigative Analyst/Legal Project Manager for Crivella West Incorporated as an advanced analytics and investigational research company. He has over ten years experience managing all aspects of electronic discovery including collection, search, review and production. Vince has been the lead ESI project manager for some of the largest Mass Tort Class Action Pharmaceutical litigations in the country and also has experience with Bankruptcy, Antitrust, Securities, Commercial and Employment Law matters.



Vince has drafted various discovery pleadings including Document Preservation Orders, Legal Hold Notices and Electronically Stored Information (ESI) Document Production Protocols. Vince has also drafted declarations and affidavits regarding the quality and sufficiency of document productions and has attended status conferences in State and Federal court to support the related motions. Vince has attended numerous Federal Rule of Civil Procedure 26(f) Meet and Confer sessions to assist in the negotiation of ESI protocols and search criteria.

Prior to law school, Vince graduated from Robert Morris University in 1995 with a B.S.B.A. degree in Finance/Economics. He is admitted to practice law in the State of Pennsylvania as well as the United States District Courts in the Western Pennsylvania. Vince attained his Project Management Professional PMP(r) certification in March 2015.

Timothy Clark

thesandersfirm.com/attorneys/timothy-clark/

Timothy Clark, simply Tim to friends, is a third generation trial lawyer admitted to the California Bar. He recently joined the law firm of Sanders Phillips Grossman, LLC. He received his J.D. from the University of San Diego School of Law and graduated with honors from Chapman University.

Mr. Clark began his legal career with a large, defense-oriented law firm, which provided him with invaluable insight. He transitioned to the Plaintiff's Bar by joining the prestigious LA-based trial firm Engstrom, Lipscomb & Lack focusing much of his time over those years on pharmaceutical and medical device litigation. He has exercised leadership roles in all facets of litigation in coordinated proceedings, with a particular focus on developing the building blocks to establish General Causation, which is often times the most difficult obstacle to hurdle in a pharmaceutical case.



Mr. Clark has extensive knowledge of medical device and pharmaceutical regulations. Specifically, Mr. Clark has working knowledge of pharmaceutical product pre-approval development, with detailed understanding on Non-Clinical Studies and Clinical Trials, and post-approval obligations and requirements, including Safety Surveillance and Pharmacovigilance and ongoing Clinical Trials. His understanding of the FDA-drug sponsor relationship enables him to tailor successful strategies and arguments in discovery battles in order to procure materials Plaintiffs and their experts need to get the job done.

Mr. Clark has developed experts spanning from molecular biology and non-clinical animal modeling and scale up to oncology and pathology to epidemiology, biostatistics, and meta-analysis. His experience and perspective helps him tailor his approach to each case to secure the best result for his clients. His areas of practice include products liability, pharmaceutical and medical device litigation, mass tort litigation, personal injury, insurance bad faith, and civil litigation. When not advocating for his clients, Tim spends his time with his wife Ashley and daughter Kirra and surfs as much as possible.

Eric Gibbs

classlawgroup.com/attorneys/gibbs/

Eric Gibbs prosecutes consumer protection, whistleblower, antitrust, and mass tort matters. He has been appointed as lead counsel, class counsel, and liaison counsel in dozens of contested, high profile class actions and coordinated proceedings, and currently serves in leadership positions in *In re Am. Honda Motor CR-V Vibration Litigation*, *In re Anthem, Inc. Data Breach Litigation*, *In re Risperdal and Invega Product Liability Cases*, *In re Hyundai Sonata Engine Litigation*, and *In re Vizio, Inc., Consumer Privacy Litigation*. Eric has recovered nearly a billion dollars for the clients and classes he represents, and has negotiated groundbreaking settlements that resulted in meaningful reforms to business practices, and have favorably shaped the laws impacting plaintiffs' legal rights.

In over twenty years of practice, Eric has developed a distinguished reputation with his peers and the judiciary for his ability to work efficiently and cooperatively with co-counsel, and professionally with opposing counsel in class action litigation.

Eric has been widely recognized for his professional excellence and achievements, and has been selected by numerous publications as a leading lawyer in the field of Class and Mass Actions.

The *Daily Journal* named Eric to its prestigious list of "Top Plaintiff Lawyers in California" for 2016. Consumer Attorneys of California selected Eric and co-counsel as finalists for the Consumer Attorney of the Year award for their work in achieving \$100 million settlement in the Chase "Check Loan" Litigation.

His cases have been chronicled in major legal and news publications including *NBC News*, *CNN*, the *National Law Journal*, *The New York Times*, *Auto Week*, *Market Watch*, and *Bloomberg News*.

Eric holds a variety of leadership positions in professional associations dedicated to consumer advocacy, and he is frequently called upon to present on developing trends in the law at conferences throughout the country.



Mark P. Glago

glagolawfirm.com/staff/mark-philip-gлаго/

Attorney Mark Glago graduated from the University of Richmond in Virginia with Phi Beta Kappa honors, having triple-majored in Political Science, Speech and Sociology. He was the University's Rhodes Scholar nominee and received the "Most Outstanding Graduate" award. At the Tulane University School of Law, he was Managing Editor of the Tulane Law Review and again graduated with honors.



Over the past ten-plus years, Mr. Glago has handled over 2,500 cases and been the "first-chair" lawyer for over 160 trials in Louisiana courts. He has built a respected, full-service law firm devoted to recovering compensation for clients in a range of practice areas such as class actions, wrongful death, medical malpractice, commercial litigation, and other situations. We invite you to review our notable trials and settlements.

Mr. Glago is licensed to practice in Louisiana and Texas state courts and all Louisiana federal courts. He serves on the Executive Committee of the Class Action Division of the Louisiana Bar Association. He is the current Chairman of the Insurance Law Division of the Louisiana Association of Justice (formerly the Louisiana Trial Lawyers Association). He is also active in the New Orleans Bar Association, Texas Bar Association, Houston Bar Association and the American Trial Lawyers Association. He has been honored as a Louisiana Superlawyer from years 2012 – 2017 and received a St. Charles Magazine Top Lawyers in New Orleans Award. For more details on his background, follow the link below. If you need representation in New Orleans or Southeast Texas, please contact us

THE OPIOID EPIDEMIC: A 'MASS FATALITY CATASTROPHE'

MEDICAL AND LEGAL IMPLICATIONS



VICKI MANIATIS, ESQ.
JOHN RESTAINO, DPM, JD, MPH
SANDERS PHILLIPS GROSSMAN

OPIOIDS

- ▶ Class of drugs that target the opioid receptors in the brain and are used to reduce pain.
- ▶ Prescription opioids such as hydrocodone and oxycodone as well as illicit drugs like heroin.

COSTS

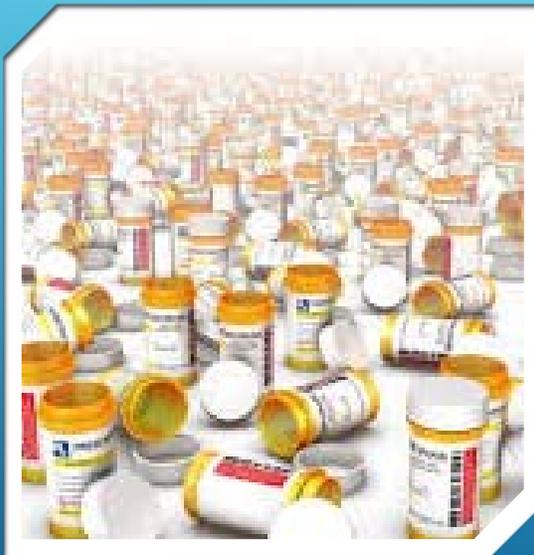
- ▶ Total economic burden est. \$78.5 billion.
 - ▶ 28.9 billion for increased health care and substance abuse treatment costs .
 - ▶ ~20 billion is borne by the public sector in health care, substance abuse treatment, and criminal justice costs.
 - ▶ ~\$20 billion in emergency department and inpatient care for opioid poisonings.
- ▶ The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care, 2016; 54 (10): 901

MASS FATALITY DEBACLE

- ▶ The death toll from opioids over the next decade could top 650,000.
- ▶ That's almost as many Americans as will die from breast cancer and prostate cancer during that time period.
- ▶ Opioids could kill nearly as many Americans in a decade as HIV/AIDS has killed since that epidemic began in the early 1980s.

- ▶ Narcotics “dangerously addictive”
- ▶ Primarily reserved their long-term use for cancer patients and the terminally ill.
- ▶ Purdue envisioned a bigger market.

PRE-OXYCOTIN



PLAN

- ▶ Dramatic increase in the long-term use of opioids for *chronic non-cancer pain*.
- ▶ Result: 900% increase in the number of opioid prescriptions since the mid-90s.



HISTORY

- ▶ The primary cause for this is over-prescribing.
 - ▶ Why?
- ▶ Purdue & Oxycontin in 1996



"IT WAS A 'BRILLIANTLY EFFECTIVE' CAMPAIGN".

- ▶ Get more 'non-pain specialists' physicians, to prescribe opioids
- ▶ Equated the prescribing of opioids to *compassion* for people in pain.



- ▶ OxyContin was approved in 1995.
- ▶ Purdue began marketing OxyContin in 1996.

OXYCONTIN



HISTORY

- ▶ Purdue implemented an aggressive marketing campaign:
 - ▶ Primary care providers
 - ▶ Use in non-cancer pain
 - ▶ Musculoskeletal pain; post-operative pain
 - ▶ Use as “first-line” therapy for chronic pain
 - ▶ Physician-directed advertising
 - ▶ Medical journals; conferences; video
- ▶ Certain promotional claims cited by Division of Drug Marketing, Advertising, and Communications (DDMAC)

SALES

- ▶ Sales of OxyContin grew from \$48 million in 1996 to almost \$1.1 billion in 2000.
- ▶ Eventually, OxyContin became the most prescribed Schedule II narcotic drug in the United States.

PR Newswire

May 31, 1996, Friday - 15:47 Eastern Time

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

MAY, 1996 RELEASE OF OXYCONTIN

Purdue Pharma L.P., a leader in pain management, today announced that long-acting OxyContin Tablets (for the treatment of moderate to severe pain lasting more than a few days) is available in U.S. pharmacies with a doctor's prescription.

OxyContin – the first and only 12-hour oxycodone analgesic

1996 RELEASE OF OXYCONTIN

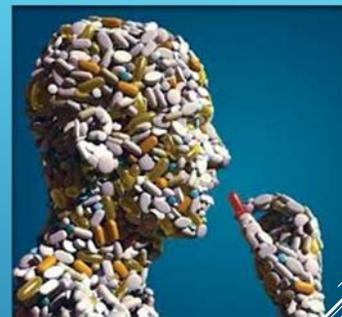
Unlike short-acting pain medications, which must be taken every 3 to 6 hours – often on an "as needed" basis -- OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night. Dosing with OxyContin Tablets on a regular schedule spares patients from anxious "clock-watching" when pain must be controlled over long periods.

1996 RELEASE OF OXYCONTIN

Twice-daily dosing simplifies and improves patients' lives
"The importance of pain control with twice-daily dosing can't be stressed strongly enough," reported Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma**. "Until now, patients with persistent pain had to take products such as Percocet(R), Vicodin(R), and Tylenol(R) with Codeine as often as six times a day. Now, with every twelve-hour OxyContin dose, many patients may experience pain relief and may enjoy daytime activities and nighttime rest without the inconvenience of taking tablets every four to six hours. Moreover, we've discovered that

▶ Purdue was effective in framing the issue as being a problem of two groups:

- ▶ People in pain
 - ▶ Some 100,000,000 Americans suffer from 'chronic pain'
- ▶ Drug addicts.



EFFECT OF MARKETING CAMPAIGN

HISTORY

- ▶ In 2004, unintentional overdose had overtaken AIDS and homicide on the overall U.S. mortality tables.

INCREASED DRUG-RELATED DEATHS

- ▶ In 2006, CDC noted that increasing prescription numbers were leading to increased drug-related deaths.
- ▶ By 2009, physicians wrote more than 6 million prescriptions for OxyContin.
 - ▶ Retail sales of the drug reached \$3 billion.
- ▶ By 2011, that number had hit 219 million.

HOWEVER...

- ▶ OxyContin's stunning success masked a fundamental problem:
- ▶ The drug wears off hours early in most people.



- ▶ Purdue has known about the problem for decades.
- ▶ Clinical trials showed many patients weren't getting 12 hours of relief.



LIABILITY STORY

- ▶ OxyContin's market dominance and its high price — up to hundreds of dollars per bottle — hinge on its 12-hour duration.
- ▶ Without that, it offers little advantage over less expensive painkillers.



- ▶ Label language suggestive of OxyContin having lower abuse potential

LIABILITY STORY

- ▶ Late 1990's, physicians began prescribing OxyContin at shorter intervals.
- ▶ LA Times reports that "*Purdue executives mobilized hundreds of sales reps to 'refocus' physicians on 12-hour dosing.*"



▶ "*Anything shorter needs to be nipped in the bud. NOW!!*"



- ▶ OxyContin taken at 12-hour intervals could be "*the perfect recipe for addiction.*"
- ▶ Theodore J. Cicero, neuropharmacologist, Washington University School of Medicine

LIABILITY STORY

- ▶ When Oxy wears off, patients can suffer body aches, nausea, anxiety and other symptoms of withdrawal.
- ▶ When the agony is relieved by the next dose, it creates a cycle of pain and euphoria that fosters addiction.



WITHDRAWAL

LIABILITY STORY

- ▶ Purdue informed physicians to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours.
 - ▶ That approach creates risks of its own.
- ▶ Research shows that the more potent the dose, the greater the possibility of overdose and death.

LIABILITY STORY

- ▶ Patients in whom the drug doesn't last 12 hours can suffer both a return of their underlying pain and the beginning stages of acute withdrawal.
- ▶ *"That becomes a very powerful motivator for people to take more drugs."*
 - ▶ Theodore J. Cicero, PhD, Professor & Vice Chairman for Research Department of Psychiatry Washington University, St. Louis, Missouri

LIABILITY STORY

- ▶ Purdue's response:
 - ▶ *"Scientific evidence amassed over more than 20 years, including more than a dozen controlled clinical studies, supports FDA's approval of 12-hour dosing for OxyContin."*
 - ▶ Gail Cawkwell, MD - Purdue's chief medical officer

THE SACKLERS FAMILY

- ▶ NY family of physicians and philanthropists
 - ▶ Bought Purdue in 1952.
- ▶ Late 1980s, patent on its main source of revenue, MS Contin, a morphine pill for cancer patients, was running out.
- ▶ Executives anticipated a massive loss of revenue as generic versions drove down the price of MS Contin.

EXTENDED RELEASE

- ▶ Purdue developed a technique to stretch a drug's release over time.
- ▶ In MS Contin, the technique made morphine last eight to 12 hours.
- ▶ Purdue decided to use it on an old, cheap narcotic, oxycodone.

OXYCONTIN

- ▶ Over the next decade, Purdue sunk more than \$40 million into development of OxyContin

EARLY CLINICAL TRIALS

- ▶ The 1st patients to use OxyContin: women who underwent surgery at two hospitals in Puerto Rico in 1989.
- ▶ Purdue designed and oversaw the clinical trial
- ▶ 90 women were given a single dose of the drug while other patients were given short-acting painkillers or placebos.
- ▶ More than one-third given OxyContin started complaining about pain in the first 8 hours.

- 
- ▶ Approx. 50% required more medication before the 12-hour mark.
 - ▶ FDA analysis found that OxyContin was *"safe, relieved pain and lasted longer than the short-acting painkillers"*.

EARLY CLINICAL TRIALS

LIABILITY STORY

- ▶ 1992 submission to the Patent Office, Purdue portrayed OxyContin as a medical breakthrough that controlled pain for 12 hours *"in approximately 90% of patients."*
- ▶ Applying for a separate patent a few years later, Purdue said that once a person was a regular user of OxyContin, it *"provides pain relief in said patient for at least 12 hours after administration."*

EARLY CLINICAL TRIALS

- ▶ However, in clinical study after study, many patients given OxyContin every 12 hours would ask for more medication before their next scheduled dose.

EARLY CLINICAL TRIALS

- ▶ One study: 164 cancer patients
 - ▶ One-third given OxyContin dropped out
 - ▶ They found the treatment "*ineffective*"
- ▶ Researchers then changed the rules of the study to allow patients to take supplemental painkillers, known as "*rescue medication*," in between 12-hour doses of OxyContin.

EARLY CLINICAL TRIALS

- ▶ Study of 87 cancer patients, "*rescue was used frequently in most of the patients.*"
 - ▶ 95% patients ultimately resorted to the rescue drug
- ▶ Despite the results of the clinical trials, Purdue continued developing OxyContin as a 12-hour drug.

MISREPRESENTATION IN MEDICAL JOURNALS

- ▶ After OxyContin hit the market in 1996, ads in medical journals left no ambiguity about how long it lasted.
- ▶ A spotlight illuminated two dosage cups, one marked 8 AM and the other 8 PM.



OXYCONTIN RELEASE

- ▶ Purdue spent \$207 million on the OxyContin launch.
 - ▶ Doubled its sales force to 600
- ▶ Sales reps pitched the drug to family doctors and general practitioners
 - ▶ For back aches and knee pain.

OXYCONTIN RELEASE

- ▶ Their hook was the convenience of *"twice-a-day dosing"*.
- ▶ OxyContin *"spares patients from anxious 'clockwatching'"*

OXYCONTIN RELEASE

- ▶ Pursue's sales reps showered prescribers with clocks and fishing hats embossed with "Q12h."



OXYCONTIN RELEASE

- ▶ By year 3, sales were more than double MS Contin's peak.
- ▶ By year 5, OxyContin was generating annual revenue of more than \$1 billion.
- ▶ Sales would continue to climb until 2010, when they leveled off at \$3 billion.

OXYCONTIN RELEASE

- ▶ Forbes magazine in 2015 estimated the Sacklers' worth at \$14 billion
 - ▶ Greater than the Mellons and Rockefellers.
- ▶ OxyContin's impact on the practice of medicine was similarly transformative.

FUELING THE EPIDEMIC

- ▶ Other manufacturers began marketing their own narcotic painkillers for routine injuries.
- ▶ By 2010, one out of every five doctor's visits in the U.S. for pain resulted in a prescription for narcotic painkillers
 - ▶ Johns Hopkins University study

FUELING THE EPIDEMIC

- ▶ Rates of addiction and overdose have soared alongside the rise in prescriptions.
- ▶ Purdue dispatched representatives to Virginia, Maine and elsewhere to defend its drug.
- ▶ They blamed misuse of OxyContin and insisted their pill was a godsend for pain sufferers when taken as directed.

FUELING THE EPIDEMIC

- ▶ The U.S. Justice Dept. launched a criminal investigation
 - ▶ 2007 Purdue and 3 top executives pleaded guilty to fraud for downplaying OxyContin's risk of addiction.
 - ▶ They were ordered to pay \$635 million.
- ▶ The case centered on elements of Purdue's marketing campaign that suggested to doctors that OxyContin was less addictive than other painkillers.

IT'S NOT THE 'DRUG ADDICTS' FUELING THE EPIDEMIC

- ▶ The CDC has recommended a 3-day limit on prescription painkillers for patients.
- ▶ Dependency begins within 3 days
- ▶ Patients on opioids for > 3 days have increased risk of dependency and then addiction.

IT'S NOT THE 'DRUG ADDICTS' FUELING THE EPIDEMIC

- ▶ In one study out of Utah 92% of opioid-caused deaths occurred in people using the drug for legitimate purposes.
- ▶ However, some 80% of these individuals were 'addicted' to the drugs.

GROUPS AT RISK: < 40 YEARS/AGE

- ▶ Usually start with legitimate medical usage
- ▶ Many young people who have a chronic underlying disorder or disease prescribed opioids until they were addicted.
- ▶ Another component of young patients prescribed the opioid for a legitimate purpose enjoyed the 'buzz', went on to abuse the drugs recreationally.

GROUPS AT RISK: < 40 YEARS/AGE

- ▶ Once addicted, it becomes harder and harder to obtain the pills
- ▶ Physicians don't like to prescribe a large number of opioids
- ▶ Opioids very expensive on the street.

GROUPS AT RISK: < 40 YEARS/AGE

- ▶ Can result in agonizing pain during the withdrawal phase.
- ▶ Many young patients will switch to heroin
 - ▶ Cheaper and more available.
- ▶ This, in turn, has led to the inflow of heroin into areas where it previously was not a problem.

THE EPIDEMIC BUILDS

- ▶ Purdue sales reps repeatedly told that the drug didn't last 12 hours.
- ▶ Reps wrote that many physicians were prescribing it for three or even four doses a day.
- ▶ Purdue worried that if OxyContin wasn't seen as a 12-hour drug, insurance companies and hospitals would balk at paying hundreds of dollars a bottle.

THE EPIDEMIC BUILDS

- ▶ *"I am concerned that some physicians are using OxyContin on a q8h schedule rather than a q12h schedule."*

- ▶ Windell Fisher, (Regional Manager in Atlanta) November 1996 — 11 months after OxyContin went on sale.

...this works but for you.

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2h schedule. Where this is occurin
ch it, convincing the physician that
ients in the studies had pain relief c

THE EPIDEMIC BUILDS

- ▶ *"Where this is occurring you need to train the representative on how to deal with it, convincing the physician that there is no need to do this, and that 100% of the patients in the studies had pain relief on a q12h dosing regimen."*

- ▶ Windell Fisher, to a District Manager
- ▶ By 2000, one in five OxyContin prescriptions was for use every eight hours, or even more frequently.

THE EPIDEMIC BUILDS

- ▶ Purdue held closed-door meetings to retrain its sales force on the importance of 12-hour dosing.
- ▶ *"These numbers are very scary,"* managers warned sales reps during one workshop.

THE EPIDEMIC BUILDS

- ▶ *"There is no Q8 dosing with OxyContin,"* one sales manager told her reps, according to a memo cited in an FDA filing.
- ▶ She added that 8-hour dosing *"needs to be nipped in the bud. NOW!!"*

Important?

- ▶ Managed care companies are denying or will start denying shorter prescriptions
- ▶ Some pharmacies are refusing to fill any prescription that is otherwise

2001 WORKSHOP PRESENTATION

THE EPIDEMIC BUILDS

- ▶ The company charged wholesalers on average about \$97 for a bottle of the 10mg pills.
- ▶ The maximum strength, 80mg, ran more than \$630.
- ▶ Commissions and performance evaluations for the sales force were based in part on the proportion of sales from high-dose pills.

THE EPIDEMIC BUILDS

- ▶ Higher doses meant more money for Purdue and its sales reps.
- ▶ A West Virginia supervisor told one of his highest performing sales reps in a 1999 letter that she could "*blow the lid off*" her sales and earn a trip to Hawaii if she persuaded more doctors to write larger doses.

Date: August 19, 1996

Re: June Sales Review

\$\$\$\$\$\$\$\$\$\$\$\$\$\$\$ It's Bonus Time in the Neighborhood!

Sales Highlights

Our June sales volume came in at \$524,000. This gives us a 12 on 12 Dollar sales growth of \$1,133,000 and ranks us #7 in volume and #8 in growth! We did 120% of our quota and had a District Average bonus of 7,400.00!

Congratulations on the most successful quarter in the history of the New South Atlantic District!

THE EPIDEMIC CONTINUES

- ▶ The Oklahoma University College of Medicine found in 2002 that nearly 87% of those prescribed OxyContin at a school pain clinic were taking it more frequently than every 12 hours.
- ▶ The reason was "*perceived end-of-dose failure.*"

THE EPIDEMIC CONTINUES

- ▶ Janssen Pharmaceutica researchers surveyed chronic pain patients treated with OxyContin
 - ▶ Reported that less than 2% said the drug lasted 12 hours
 - ▶ Approx. 85% said it wore off before eight.

THE EPIDEMIC CONTINUES

- ▶ San Francisco public health clinics stopped dispensing the OxyContin in 2005.
- ▶ Based their decision, in part, on feedback from patients who said it wore off after eight hours.
- ▶ The clinics switched to generic morphine, which has a similar duration and costs a lot less.

PATIENTS FIGHT BACK

- ▶ Hundreds of lawsuits were filed by OxyContin users and their families.
- ▶ However, they never got before a jury.
- ▶ Purdue got suits dismissed by asserting, among other defenses, the *Learned Intermediary Doctrine*.
 - ▶ Thus, a new approach is needed.

2004 REGULATORY ACTIONS

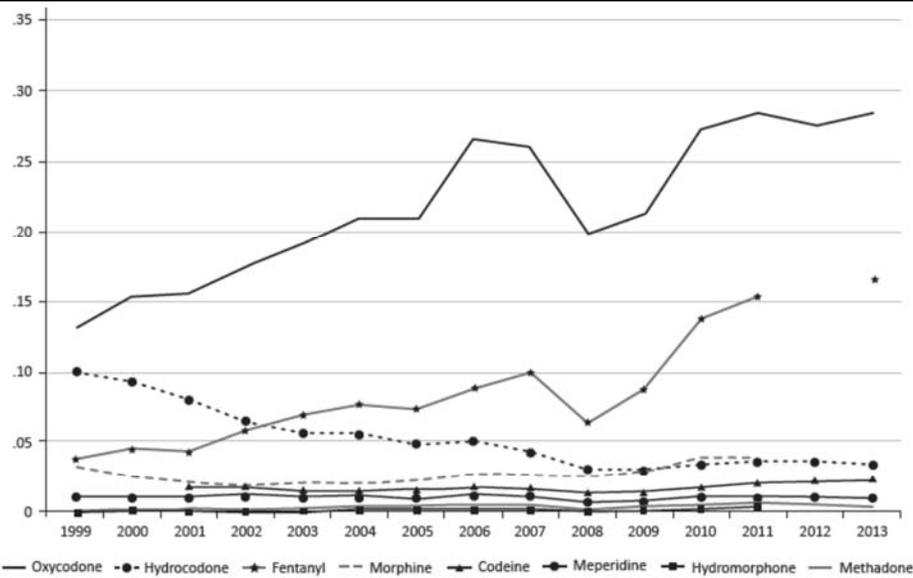
- ▶ Purdue's regulatory attorneys in Washington, D.C., made a blunt admission to the FDA:
- ▶ The 12-hour dosing schedule is, at least in part, about money.
- ▶ *"The 12 hour dosing schedule represents a significant competitive advantage of OxyContin over other products,"* the lawyers wrote.

"THE HIGHER YOU GO, THE MORE LIKELY YOU ARE TO DIE"

- ▶ OxyContin is still hugely popular.
- ▶ Doctors wrote 5.4 million prescriptions for it in 2014.
- ▶ 80% were for 12-hour dosing.
- ▶ Many patients are taking the drug at doses that public health officials now consider dangerously high.

"THE HIGHER YOU GO, THE MORE LIKELY YOU ARE TO DIE"

- ▶ Guidelines issued this year by the CDC urged physicians to "avoid" or "carefully justify" prescriptions of that strength.
- ▶ *"It's really concerning...The higher you go, the more likely you are to die."*
 - ▶ Dr. Debra Houry, Director, CDC's National Center for Injury Prevention and Control,



Note: codeine distribution not available in 2000; fentanyl, hydromorphone, and morphine not available in 2012.

Figure 1. Rate (morphine milligram equivalent kg per 10,000 persons) of distribution of opioids, Puerto Rico, Automation of Reports and Consolidated Orders System, 1999-2013

- ▶ April 20, 2017 feds announced that they will provide the states with nearly half a billion dollars for prevention and treatment programs aimed at confronting the opioid epidemic, which was described as a "*crisis*."
- ▶ Puerto Rico's share is of \$4.8 million.



FENTANYL LITIGATION

FENTANYL

- ▶ Similar to morphine but is 50 to 100 times more potent.
- ▶ Powerful synthetic opioid analgesic
- ▶ Typically used to treat patients with severe pain or to manage pain after surgery.
- ▶ It is also sometimes used to treat patients with chronic pain who are physically tolerant to other opioids.

HOW USED

- ▶ Prescription fentanyl is administered via injection, transdermal patch, or in lozenges.
- ▶ However, the fentanyl and fentanyl analogs associated with recent overdoses are often produced in clandestine laboratories.



- ▶ Opioid receptors are also found in the areas of the brain that control breathing rate.
- ▶ High doses of fentanyl can cause breathing to stop completely which can lead to death.

WHY IS FENTANYL SO DANGEROUS

SARAH FULLER CASE

- ▶ Sarah suffered for a decade with head and neck pain from two car accidents.
- ▶ Her physician asked her to come in to discuss a new prescription for her chronic pain.
- ▶ A drug company sales representative did most of the talking.

SARAH FULLER CASE

- ▶ She was given Subsys, a fast-acting opioid that is 50 times more potent than heroin.
- ▶ Fifteen months later, her fiancé found her dead in their home in Stratford.

SARAH FULLER CASE

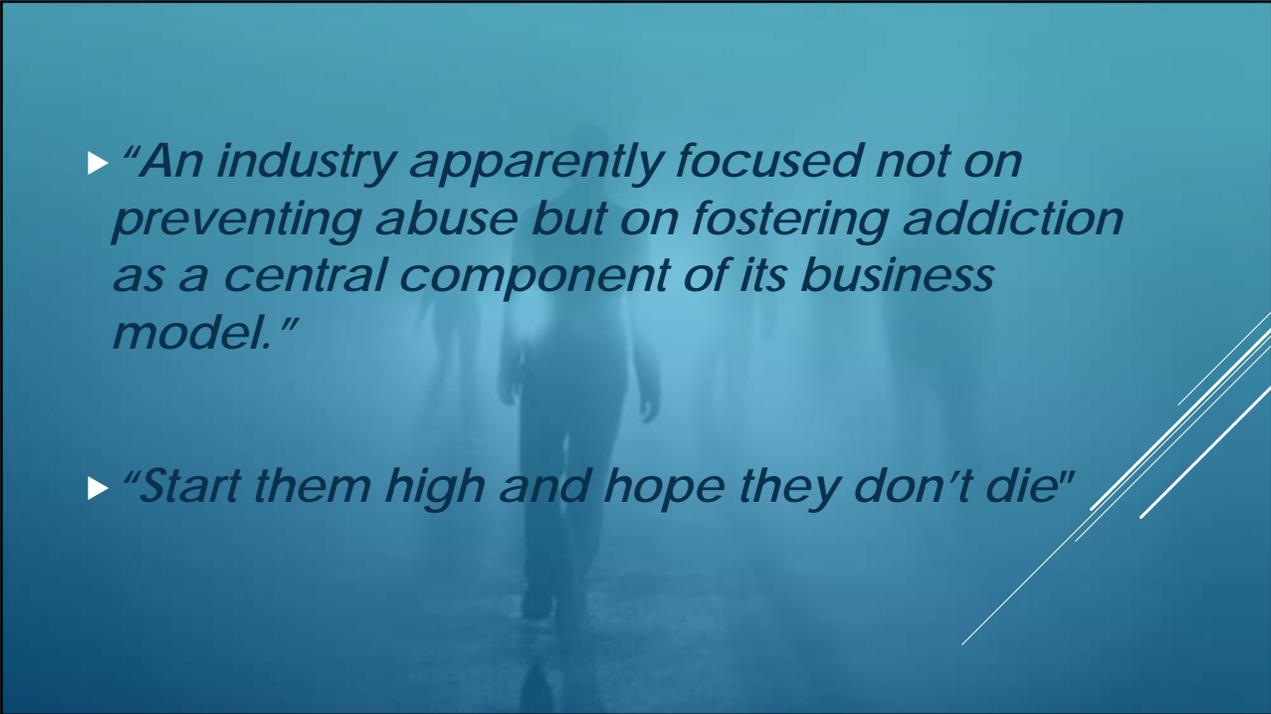
- ▶ Sarah Fuller's father recalled that the Insys sales rep described the drug as a treatment for chronic pain.
- ▶ Never mentioned that the FDA approved it only for severe cancer pain.

SARAH FULLER CASE

- ▶ Sarah would have to take it every 4-hours, 6 times a day.
- ▶ Her parents said she would set the alarm clock at night and would begin shaking if she was just a few minutes late.
- ▶ Monthly supplies would be delivered in big boxes by FedEx.

SARAH FULLER CASE

- ▶ Deborah Fuller said her disabled daughter was covered by Medicare.
- ▶ It paid out more than a quarter-million dollars for Subsys between January 2015 and her death in March 2016.

- 
- ▶ *“An industry apparently focused not on preventing abuse but on fostering addiction as a central component of its business model.”*
 - ▶ *“Start them high and hope they don’t die”*