



The Unique Impact of the Opioid Crisis in the United States—What You Need to Know

*Presented by the Widener University
Delaware Law School Food and Drug Law Association*

**Wednesday, October 23, 2019
4:00–6:00 p.m.**

Delaware Law School

delawarelaw.widener.edu

Food and Drug Law CLE Symposium
Wednesday, October 23, 2019
4:00 - 6:00 p.m.

3:30 p.m. REGISTRATION CHECK-IN

4:00 – 6:00 p.m. **“The Unique Impact of the Opioid Crisis in the
United States – What You Need to Know”**

Speakers include:

- . **The Honorable John P. Capuzzi Sr.**
Delaware County Court of Common Pleas
Topic: Ethical Issues in the Drug Courts and Role of the Judiciary
- . **Gregory Heller, Esquire**
Young Ricciuti Caldwell & Heller, LLC
Topic: Case Review & Status
- . **Co-Moderator: Christopher Mondics**
Legal Affairs Correspondent, *Philadelphia Inquirer*
- . **Stephen A. Sheller, Esquire**
Sheller, P.C.
Topic: Multidistrict Litigation Focusing on the Ethical Bias Motion;
Case Review & Status
- . **Co-Moderator: Roseann B. Termini, Esquire**
Food and Drug Law Legal Scholar; National Speaker;
Teaches Online Food and Drug Course, Widener
University Delaware Law School
Topic: Ethical Issues for Both Judiciary and Attorneys

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WIRELESS ACCESS INFORMATION AS A “WIDENER GUEST”

WIDENER UNIVERSITY DELAWARE LAW SCHOOL
Ruby R. Vale Moot Courtroom
WEDNESDAY, October 23, 2019

Username: opioids
Password: fdla19

BIOGRAPHIES

The Honorable John P. Capuzzi Sr.

The Honorable John P. Capuzzi, Sr. was sworn in January 3, 2012 to a ten-year term on the Delaware County Court of Common Pleas. Judge Capuzzi earned a BA and MBA at LaSalle University. He obtained his Juris Doctor from the Delaware Law School of Widener University in 1988. Judge Capuzzi is admitted before the Supreme Court of the United States, the Pennsylvania Supreme Court, and the Federal Court for the Eastern District of Pennsylvania.

Judge Capuzzi is a Life Member and Past President of Yeadon Fire Company No. 1. He served as President of Yeadon Borough Council from 1982 through 1989 and as the First Ward Commissioner for Marple Township from 2000 through 2005. Judge Capuzzi has served as President of the Guy G. de Furia American Inn of Court. In 2012, Judge Capuzzi was presented with the Guy G. de Furia Award in recognition of his outstanding legal ability, professionalism and high ethical standards.

From 1988 through 2005, Judge Capuzzi served as a Deputy Attorney General in the Torts Litigation Section of the Pennsylvania Office of Attorney General. During that time, he litigated major, complex cases for various state agencies.

Starting in 2006, Judge Capuzzi served as the Magisterial District Judge for Marple Township and Haverford Township. From 2006 to 2011, he was a partner in the law firm of Imperatrice, Amarant, Capuzzi & Bell, P.C.

As a practicing attorney, Judge Capuzzi was AV rated (highest legal ability and ethical standards) in Martindale Hubbell.

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Gregory Heller, Esquire

Greg Heller has litigated numerous personal injury cases that have resulted in multimillion-dollar recoveries for his clients. Like the other members of the firm, he concentrates his practice in catastrophic personal injury litigation and health care law.

Mr. Heller has substantial experience in a number of different practice areas, including trucking and highway accidents, highway design cases, premises liability, medical malpractice cases, dram shop cases, product liability cases, construction cases and managed care liability cases. He has recovered over \$20 million from insurance companies that have acted in bad faith. Mr. Heller also has experience as litigation counsel for privately held businesses in a variety of commercial disputes.

Mr. Heller has been a pioneer in the area of managed care accountability, especially when it comes to holding managed care companies accountable in court for placing profits ahead of patients. He is particularly interested in the public health and public safety implications of managed care practices. Much of his recent work in this area has involved mental health and addiction treatment, because managed care abuses are so prevalent in this area, and because managed care misconduct in this area has such significant public health consequences. He is currently one of the lawyers representing

a nationwide class of patients challenging a managed care company's unlawful refusal to cover autism treatment.

Mr. Heller has served as a consultant for the National Alliance for Model State Drug Laws, in work funded by grants to the National Alliance from the United States Department of Justice's Bureau of Justice Assistance. His clients in this area have included the District Attorneys Association of Pennsylvania, the County Commissioners Association of Pennsylvania, and other organizations concerned with public safety and public health. He was directly involved, as counsel for patient advocacy groups, in the negotiations that led up to the passage of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

Greg is directly involved as counsel for patient advocacy groups in current efforts surrounding the implementation of the Patient Protection and Affordable Care Act of 2010 and the shaping of the regulations that are necessary to give effect to much of that Act.

In May 2010, Greg received the Brian H. Early Award from the Richard J. Caron Foundation, in recognition of his accomplishments in improving access to addiction treatment.

Mr. Heller has written articles for a number of key publications in the legal profession. He has lectured on managed care issues for the Pennsylvania Bar Institute and the Pennsylvania Association for Justice, and he has testified on these issues before the judiciary committee of the Pennsylvania House of Representatives. He was recently invited to become a Fellow of the American Bar Foundation, which is an honorary organization of lawyers, judges and legal scholars "whose public and private careers have demonstrated outstanding dedication to the welfare of their communities and to the highest principles of the legal profession."

Mr. Heller is a member of the American Association for Justice (formerly the Association of Trial Lawyers of America), the Pennsylvania Association for Justice (where he serves on the Amicus Curiae committee), the Philadelphia Trial Lawyers Association, the American Bar Association, the Pennsylvania Bar Association and the Philadelphia Bar Association. He has served on the board of the Legal Clinic for the Disabled and has served as a Co-Chair of the Philadelphia Bar Association's Language Access Task Force.

Mr. Heller, like all the members of Young Ricchiuti Caldwell & Heller, is a member of the Million Dollar Advocates Forum, a forum restricted to lawyers who have had primary responsibility in securing a recovery in excess of \$1 million. The Martindale-Hubbell Legal Directory has given Mr. Heller its highest rating.* He is admitted to practice before the United States Supreme Court, Pennsylvania courts and the United States Patent and Trademark Office. He received his undergraduate degree in physics from Williams College and his Juris Doctorate cum laude from the University of Michigan Law School, where he was managing editor of the Michigan Law Review and received several awards for legal scholarship.

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facilitator of a peer review rating process. Ratings reflect the anonymous opinions of members of the bar and the judiciary. Martindale-Hubbell® Peer Review Rating™ fall into two categories - legal ability and general ethical standards.

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Christopher Mondics

Chris Mondics is a legal affairs journalist based in Philadelphia and is currently at work on a book about the opioid epidemic. He has written extensively about the ongoing debate over U.S. civil forfeiture laws, claims by victims that the government of Saudi Arabia bears responsibility for the Sept. 11, 2001 attacks and other subjects. Before returning to Philadelphia in 2007 to cover legal affairs for the *Philadelphia Inquirer*, he was a Washington correspondent for the paper covering the impeachment of President Clinton, the 9/11 attacks, and several presidential campaigns and other subjects. In addition to the *Inquirer*, his work has appeared in the *Los Angeles Times*, the *Washington Post*, and other publications in the U.S and abroad.

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Stephen A. Sheller, Esquire

Stephen A. Sheller is the founding partner of Sheller, P.C., one of the leading whistleblower, plaintiff's product liability, personal injury, class action and whistleblower/qui tam law firms in the United States.

Mr. Sheller and his firm represent clients throughout the United States. His practice includes pharmaceutical products injury, whistleblower/qui tam litigation, consumer protection, class actions, complex catastrophic personal injury, consumer products liability, medical device product and mass tort litigation.

His long and storied career can be summed up in a few words: a principled, fervent champion for those harmed by the negligence or intentional acts of corporations or others, in need of a strong legal voice.

ACHIEVING HISTORIC VERDICTS & SETTLEMENTS

Mr. Sheller has been at the forefront of celebrated national lawsuits, representing pharmaceutical whistleblowers and recovering over \$6.25 billion for the U.S. government: most recently a \$7.3 million whistleblower settlement with Astellas Pharma in April 2014, and other, historic whistleblower settlements including \$2.2 billion against Johnson & Johnson in 2013, \$520 million against AstraZeneca in April 2010, \$2.3 billion against Pfizer Inc. in September 2009 and \$1.4 billion against Eli Lilly & Company in January 2009. Serving as a lead attorney in these recent pharmaceutical whistleblower cases, these are among the top fifteen civil and criminal settlements in U.S. history. Mr. Sheller continues to work with whistleblowers and is recognized as one the country's premier experts on qui tam whistleblower and False Claims Act cases.

DEFENDING THE RIGHTS OF VOTERS

In November 2000, Mr. Sheller instituted litigation in Palm Beach County, Florida involving butterfly ballots and the 2000 Bush v. Gore U.S. Presidential election. As a result, he was featured in national, regional and local media for his role as a lead attorney challenging the poll results. Mr. Sheller argued that the Broward and Palm Beach County ballots were unconstitutional, denying citizens their rights to vote. Sheller alleged that if a proper analysis had been conducted, it would have been proven that Al Gore won the election by several thousand votes.

Mr. Sheller filed a law suit on behalf of Pennsylvania's American Civil Liberties Union (ACLU), and won the right, at the Pennsylvania Supreme Court, for students to vote in the towns and cities where they went to college if it differed from their home residences.

BRINGING JUSTICE FOR THOSE INJURED BY PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Mr. Sheller also has an ongoing dedication to representing clients injured by defective drugs. His representation of children injured by antipsychotic drugs was profiled on the CBS Evening News. He recently filed cases in Pennsylvania and New Jersey on behalf of clients harmed by antipsychotic drugs Risperdal and Invega. Boys and young men who took the drug developed gynecomastia, growth of breasts, requiring mastectomy removal. In addition to naming pharmaceutical companies, Mr. Sheller named the "ghostwriting" company who wrote the medical literature that promoted the drugs alleging they knew or should have known of the dangerous side effects. Naming the "ghostwriting" company puts corporations on notice they cannot obscure the risks of drugs by engaging a third party to write supposedly "impartial" medical articles. One of the first if not the first time, naming the "ghostwriters" demonstrates a creative approach to pharmaceutical product liability lawsuits.

Mr. Sheller is currently mounting national class action on behalf of clients in pharmaceutical drug and medical device injury, whistleblower qui tam cases and other matters.

INVOLVEMENT & RECOGNITION FROM THE PROFESSION

June 2017, Mr. Sheller received an honorary degree from Drexel University, Doctor of Humane Letters, at Citizen's Bank Ball Park in Philadelphia, PA. Drexel bestowed this honor for his work as a "champion of the disenfranchised," representing those harmed by the negligence or intentional acts of corporations or others and in need of a strong legal voice.

"An American Hustle: Whistleblowers & Prosecuting False Claims Cases" was the title of Mr. Sheller's address as the featured CLE speaker for the Montgomery County Bench Bar Conference held at the Hyatt Regency Chesapeake Bay Golf Resort in Cambridge, Maryland on September 13, 2014.

In February 2015 at a gala event in Los Angeles, Mr. Sheller was presented with the "Humanitarian of the Year" award from the Citizens Commission for Human Rights. He was honored for his career-long dedication to justice for clients injured by

pharmaceutical drugs. Actor Ann Archer presented the award following a video of Mr. Sheller, who then addressed the audience of 1,000. He presented an in-depth seminar to the organization's Board of Directors the following day.

Mr. Sheller was selected for inclusion in the 2015 "Best Lawyers in America" guide for legal excellence in the Mass Tort Litigation/Class Actions - Plaintiffs and Qui Tam Law" practice areas.

Selected as a Pennsylvania "Super Lawyer," Mr. Sheller has been honored each year since the award's inception in 2003, and in 2010, 2011, 2012 and 2013 was recognized as both a Top 100 Philadelphia and Top 100 Pennsylvania SuperLawyer.

In 2003 Mr. Sheller was named a finalist for the Trial Lawyer of the Year Award given by Trial Lawyers for Public Justice for discovering the light cigarette fraud and initiating the litigation strategy to remedy the deception. This innovative legal strategy resulted in a \$10.1 billion verdict against Phillip Morris.

Attorney Sheller was also invited and presented the **Edward J. Ross Memorial Lecture in Litigation at the Temple University Beasley School of Law**. His lecture, "Lawyering in Times of Saints and Evil-Doers," reminded future lawyers to always lead with their conscience and to seek fairness and justice over personal gain. His talk highlighted by newsreels and video illustrated significant mileposts in his career. As a result of Mr. Sheller's unique legal strategies now used as a model in states across the U.S., he was honored with the first annual "Pioneer Award" by the Tobacco Control Resource Center at the winter 2011 American Association for Justice conference.

PROVIDING EXPERT COMMENTARY AS A LEGAL THOUGHT LEADER

The passionate and provocative views of Mr. Sheller provide regular legal commentary on The American Law Journal television program. He has appeared nationally on ABC's "Good Morning America," CNN, MSNBC, CBS's Early Show, CBS Evening News with Katie Couric, FOX National News, three Insider Exclusive legal documentaries and all major Philadelphia-area network news programs.

Mr. Sheller is a sought-after guest lecturer on legal matters in continuing legal education courses and national legal and medical symposia. He has presented programs and sat on distinguished panels discussing whistleblower/qui tam, tobacco, pharmaceutical products, breast implants and other medical device litigation. He has been a special presenter and lecturer on law at The National Judicial College, Northeastern Law School, the 19th and 20th Conferences of the Tobacco Products Liability Project and other educational institutions. At a program sponsored by Wall Street Journal he discussed direct to consumer pharmaceutical advertising with the CEO of Pfizer and Ralph Nader.

Mr. Sheller's publications include "The Physician and Hospital as Potential Defendants in Drug and Medical Device Claims" in the legal textbook Pharmaceutical Law published by Harrison Company in 2000 and Law Review articles such as the Temple Law Review article "The Consumers Interest - Is It Being Protected by the Public Utility Commission."

Mr. Sheller is in his second term appointed as a member of the Drexel University Board of Trustees, past member of the Board of Trustees of Pennsylvania State University and past and present member of the boards of several other organizations and entities, including the Salvation Army of Greater Philadelphia, Eastern Pennsylvania and Delaware.

GIVING BACK TO THE COMMUNITY AND THE NATION AT LARGE

Visit <http://sheller.com/community-and-civic-responsibility/> to learn more about The Sheller Family Foundation Philanthropy and involvement.

Stephen Sheller and his wife Sandra are active philanthropically in Philadelphia and beyond. Their most recent endeavors through the Sheller Foundation include the new Stephen and Sandra Sheller Center for Social Justice at Temple University and the Stephen and Sandra Sheller 11th Street Family Health Services Center at Drexel University.

In August 2010, Mr. Sheller was recognized for his continued support of, and dedication to, the Pennsylvania National Guard and specifically to the troops of Operation Iraqi Freedom by Raymond T. Odierno, then U.S. Commanding General for Iraq. General Odierno had a plaque and a flag that originally flew at the U.S. Embassy in Iraq presented to Mr. Sheller.

Mr. Sheller and his wife Sandy sponsor a permanent exhibit honoring the Pennsylvania National Guard at the National Liberty Museum in Philadelphia. Entitled “Civilian in Peace/Soldier in War” the exhibit is in the museum’s “Awards of Valor” gallery.

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Roseann B. Termini, B.S., M.Ed., J.D.

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Roseann B. Termini, B.S., Ed. M., J.D. has extensive experience in food, drug, medical devices, personal care, dietary supplement, tobacco and veterinary products regulation. Ms. Termini recently published a new comprehensive edition both in print and E-book formats of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products* (2019). She published the new edition because of evolving law, novel cases and latest regulations, a full E-book that mirrors the print, as well as 12 stand-alone separate subject specific E-

books. Professional considerations, ethical issues, enforcement, criminal corporate liability and politics are covered.

See: www.fortipublications.com

Other publications span a broad array of topics including the right-to-request investigational therapies, corporate criminal liability, accountability, the Foreign Corrupt Practices Act, health claims, dietary supplements, product classification, duty to warn, preemption, promotion, tobacco, stem cells, risk assessment, labelling, globalization and e-cigarettes. Her works have been cited in other publications.

Ms. Termini is a featured speaker at international and national conferences and webinars including the Central Atlantic Association of Food and Drug Law Officials, the Pennsylvania Bar Institute (PBI), FDA News, the Food and Drug Law Institute and the Society of Cosmetic Chemists. She was selected to present at the Center for Ethics and Rule of Law Opioid Conference, was the sole speaker at a national opioid webinar and has been interviewed about this crisis. Ms. Termini is the faculty conference director of the annual “*All Matters FDA*” symposium at Delaware Law School, Widener University that addresses topics such as Marijuana, E-cigarettes, Food Safety, Claims, Homeopathic remedies, the Opioid Crisis, Foreign Corrupt Practices Act, Biosimilars, Dietary Supplement regulation, and Corporate Accountability. Presentations have included: *Opioids, GMOs, Personal Care Products, Medical Devices, Criminal Enforcement, Who Really Regulates Your Pizza, Are “Smart Labels” Really Smart and Terminology such as Natural and Healthy.*

Her writing expertise led her to an appellate clerkship, position as sole corporate pharmaceutical counsel, regulatory affairs attorney and senior deputy attorney general at the Pennsylvania Office of Attorney General (OAG) where she prosecuted cases at the trial and appellate levels and spearheaded the implementation procedures for the Pennsylvania Plain Language Act. She was the first recipient of the “Plain English” Award by the Pennsylvania Bar Association. Who’s Who recognized Ms. Termini’s excellence in the field with the Lifetime Achievement Award.

Ms. Termini has been actively involved in committees of several professional associations for several years, including her service as Chair of a Food and Drug Law Institute Committee. She is Co-Chair of the Pennsylvania Bar Assn. Health Law Committee and Vice Chair of the Disability Rights Committee. She served on the President’s Council at Immaculata University and as Vice Chancellor of the Justinian Association. Ms. Termini was appointed to the Board of the St. Thomas More Law Society and is a member of the Central Atlantic Association of Food and Drug Law Officials. Ms. Termini’s appointment to the PBA Ethics and Professional Responsibility Committee has spanned over 30 years. Her publications are available for download on the SSRN Author page link below.

Contact Details

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COURSE
MATERIALS



TREATMENT COURTS

*A Hybrid of the Traditional Criminal
Justice System*

The Honorable John P. Capuzzi, Sr.

THE GOAL

- The defined goal is to modify the behavior of the offender by offering therapeutic modalities designed to start the recovery process and to identify resources to help each one maintain that on-going process.

THE JUDGE'S ROLE

- The Judges are analogous to a wheel hub and the components that provide the services and information are the spokes.
- Consequently, a treatment court judge, pursuant to Canon 2.5 must, above all, have an in-depth understanding of the various substance abuse disorders and the psychological and psychiatric illnesses which are afflicting those before them.

The JUDGE'S ROLE cont...

- Most often, there is not one root cause by a complex intertwining of several which necessitates input from those who are trained and versed in the treatment of the particular issue.
- A casual understanding or misinformed premise by a judge relates directly a judge's competence and diligence.
- Ultimately the Judge must make an informed and reasoned disposition. That is, in the best interest of society and the defendant.

THE ESSENTIAL ELEMENTS OF OPIOID INTERVENTION COURTS

1. Broad legal eligibility;
2. Immediate screening for risk of overdose;
3. Informed consent after consultation with defense counsel;
4. Suspension of prosecution or expedited plea;
5. Rapid clinical assessment and treatment engagement;
6. Recovery support services;
7. Frequent supervision and compliance monitoring;
8. Intensive case management;
9. Program completion and continuing care; and
10. Performance evaluation and program improvement

Center for Court Innovation (courtinnovation.org)

ADDICTION DEFINED

- The National Institute on Drug Abuse (NIDA) defines addiction as: “a chronic, relapsing brain disease that is characterized by compulsive drug seeking (behavior) and use, despite harmful consequences.”
- Addiction disrupts the normal function of a previously healthy brain, causing physical changes to the brain that are critical to judgment, decision making, learning, memory, and behavior.

National Judicial Opioid Task Force (NJOTF) Resource Center: www.ncsc.org/opioids.

AGONISTS and ANTAGONISTS

- **Agonists:** drugs that activate receptors in the brain, bind to the receptors, and turn them on. Full agonist opioids activate the opioid receptors in the brain fully resulting in the full opioid effect and have the greatest abuse potential (e.g. morphine, heroin, methadone, oxycodone, or hydromorphone). (NAABT)
- **Antagonists:** drugs that bind the receptors without eliciting responses in the brain. These nullify the effects of opioids by attaching to the opioid receptors without activating them and block full agonist opioids. (Naltrexone and Naloxone). (NAABT)

BOTTOM LINE FOR COURTS

- Drugs are chemicals that interfere with the way neurons normally send, receive, and process information.
- Drugs change the brain's structure and how it works.
- These brain changes often lead to the harmful behaviors seen in people who abuse drugs.
- Drug abuse and mental illness often co-exist. (NJOTF)

Second Chance Court

Pretrial Bail Heroin Recovery Program

An Initiative of the Delaware County
Court of Common Pleas



COLLABORATIVE APPROACH

- **Pre-trial bail office**
- **Adult Probation and Parole office**
- **Office of the District Attorney**
- **Office of the Public Defender**
- **Magisterial District Courts**
- **George w. Hill correctional facility**
- **Crozer Community Hospital Access Center**
- **Court of Common Pleas**

PROBLEM

- **Heroin and opioid users are always thinking of how to obtain the next “fix,” even while they are being processed after arrest.**

OUR OBJECTIVE

- **Supervised treatment in lieu of pre-trial incarceration.**

AIM

- **Intervention beginning immediately after arrest starting at the magisterial district court.**

WHY?

- **There is an identifiable gap between the preliminary arraignment before a magisterial district judge following arrest and when the case arrives before a judge in the court of common pleas for a pretrial conference.**
- **Normally, this gap is between 4 and 6 months.**

MAIN ISSUE

- **In the gap period, there is no supervision or real method of enforcing treatment recommendations following an MDJ's order for a drug and alcohol evaluation.**

WHAT ADDICTS SAY

- In various conferences and workshops, the overwhelming sentiment has been that intervention immediately after arrest is more effective than delaying treatment until court ordered at the common pleas level.
- Don't give the addict time to get back to the environment that fostered the addiction.

TARGET POPULATION

- **Persons charged with possession of heroin or opioids and related misdemeanor offenses;**
- **No age limit; and**
- **Residents of Delaware county**

HOW IS CANDIDATE IDENTIFIED?

- **At time of bail interview prior to preliminary arraignment before magisterial district judge.**
- **If no bail interview, offender may be identified in following ways;**
 - **at GWHCF – by bail coordinator or GWHCF staff.**
 - **MDJ may flag potential eligible defendants.**
 - **police and/ or family of the offender may make referral.**
 - **defense counsel may make the referral.**

CROZER COMMUNITY HOSPITAL STAFF IMMEDIATELY NOTIFIED

- **Crozer staff notified by MDJ at time of arraignment so that the candidate may be seen promptly at access center.**
- **Crozer CRS staff will be available to transport candidate to pretrial bail office from access center, if needed.**

PROCEDURE

- **Approved and enrolled candidates, will be placed on one centralized docket in the court of common pleas and will be assigned to and continuously supervised by Common Pleas Judge Capuzzi with the assistance of bail coordinator.**
 - **Enforcement of bail for all program candidates will rest with Judge Capuzzi, including,**
 - **Bail violation hearings**
 - **Rule 150 hearings**

CONDITION OF BAIL



- **Evaluation and treatment will be part of the bail conditions set by the magisterial district judge.**
- **Non-compliance with the conditions will trigger a review in the court of common pleas.**

WHILE ON SECOND CHANCE PRETRIAL BAIL SUPERVISION

- Candidate must keep in contact with the pretrial bail coordinator while on bail – regardless of where candidate's treatment facility (or halfway house/recovery house) is located.
- Candidate will be expected to appear at all court appearances, including the scheduled preliminary hearing before the mdj.
- Stephanie Price, pretrial bail office, coordinator, will supervise candidate to ensure compliance and will notify mdj and cp judge of non-compliance.

Post Preliminary Hearing – Prior to Pretrial Conference in CP Court

- **After the preliminary hearing, enrolled candidate's case will continue to matriculate through the criminal justice system with the trial court oversight of Judge Capuzzi with the assistance of the Bail Coordinator.**
- **All trial court matters will be presided over by Common Pleas Judge.**

Common Pleas PTC Hearing

- **At PTC, candidates may elect the following:**
 - **Accept the Commonwealth’s offer for**
 - **Drug Treatment Court (this can be done any time prior to PTC). Track I, Track II**
 - **Negotiated guilty plea disposition**
 - **Enter an “open guilty plea.”**
 - **Demand a trial.**

“Second Chance” bail conditions end at time of case disposition

- **Once the candidate’s criminal case has reached a final disposition – pretrial bail supervision ends.**
- **Any and all treatment and aftercare recommendations would be recommended as a condition of a sentence should there be a finding of guilt.**

Second Chance Court Statistics

- 1103 Criminal complaints wherein the affidavit of probable cause indicate a likely opioid problem.
- 107 Persons who entered the program
- 3 Persons in the program who were lost to do an overdose
- 83 Persons who successfully transitioned; no violations within a year.

2019 Statistics as of 10/15/2019

- 311 Persons considered for the program
- 45 Persons who had an assessment for entry into the program
- 35 Persons accepted into the program
- 17 Persons currently in the program
- 37 Participants sentenced in 2019
- 9 Transitioned to Drug Treatment Court

Obstacles

- No funding for non-Delaware County residents;
- For first-time offenders with simple possession the maximum allowable sentence is less than the time necessary for Drug Treatment Court participation;
- Some ideal candidates are not arrested, but just given a summons;
- Families or friends post bail before the assessment can take place;
- Jailhouse lawyers;
- Defense lawyers who are myopic and only look for a quick out rather than the client's long-term well-being.

CRIMINAL DIVISION

COMMONWEALTH OF PENNSYLVANIA : CP-23-CR- -2019
: :
VS. : OTN:
: :
: MJ-32 -CR- -2019

ORDER

AND NOW, this _____ day of _____ 2019, upon consideration of the attached Stipulation by and between the Commonwealth of Pennsylvania, through its attorney, Michael H. Hill, Assistant District Attorney and the Defendant, through her counsel, Kenneth B. Collins, Assistant Public Defender, it is hereby **ORDERED** and **DECREED** that bail in the above-captioned matter shall be reduced from ten percent (10%) of \$15,000 to \$15,000 unsecured and shall be supervised by Court of Common Pleas Judge John Capuzzi, WITH THE FOLLOWING CONDITIONS: (1) Defendant shall undergo a drug and alcohol assessment performed by Crozer staff and shall not be released until any and all recommendations are in place, (2) Defendant must sign all releases allowing the facility and treatment providers to communicate with the Delaware County Pre-Trial Bail Office advising the Defendant is enrolled in and attending treatment sessions, not providing positive urine drug screens and appropriately participating in treatment, and (3) Defendant must successfully complete all treatment recommendations as stated in the individualized treatment plan and comply with all treatment recommendations including placements at a halfway and/or recovery house, (4) Defendant must report to the Pre-Trial Bail Office weekly as directed by the Pre-Trial Bail Coordinator.

It is further stipulated that the Defendant's failure to comply with the bail conditions and/ or treatment program will result in the Pretrial Bail Coordinator making application to Court of Common Pleas Judge John Capuzzi which may result in either the issuance Common Pleas bench warrant or immediate hearing before Judge Capuzzi to address bail compliance.

BY THE COURT:

J.

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

CRIMINAL DIVISION

COMMONWEALTH OF PENNSYLVANIA : **CP-23-CR- -2019**
: :
VS. : **OTN:**
: :
: **MJ-32 -CR- -2019**

STIPULATION

It is hereby agreed by the Commonwealth of Pennsylvania, through its attorney, Michael H. Hill, Assistant District Attorney and the Defendant, through her counsel, Kenneth B. Collins, Assistant Public Defender, that bail in the above-captioned matter shall be reduced from ten percent (10%) of \$15,000 to \$15,000 unsecured and shall be supervised by Court of Common Pleas Judge John Capuzzi, WITH THE FOLLOWING CONDITIONS: (1) Defendant shall undergo a drug and alcohol assessment performed by Crozer staff and shall not be released until any and all recommendations are in place, (2) Defendant must sign all releases allowing the facility and treatment providers to communicate with the Delaware County Pre-Trial Bail Office advising the Defendant is enrolled in and attending treatment sessions, not providing positive urine drug screens and appropriately participating in treatment, and (3) Defendant must successfully complete all treatment recommendations as stated in the individualized treatment plan and comply with all treatment recommendations including placements at a halfway and/or recovery house, (4) Defendant must report to the Pre-Trial Bail Office weekly as directed by the Pre-Trial Bail Coordinator.

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Michael H. Hill
Assistant District Attorney

Kenneth B. Collins
Assistant Public Defender



JOURNAL
for Advancing Justice

AJ Advancing
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Volume II

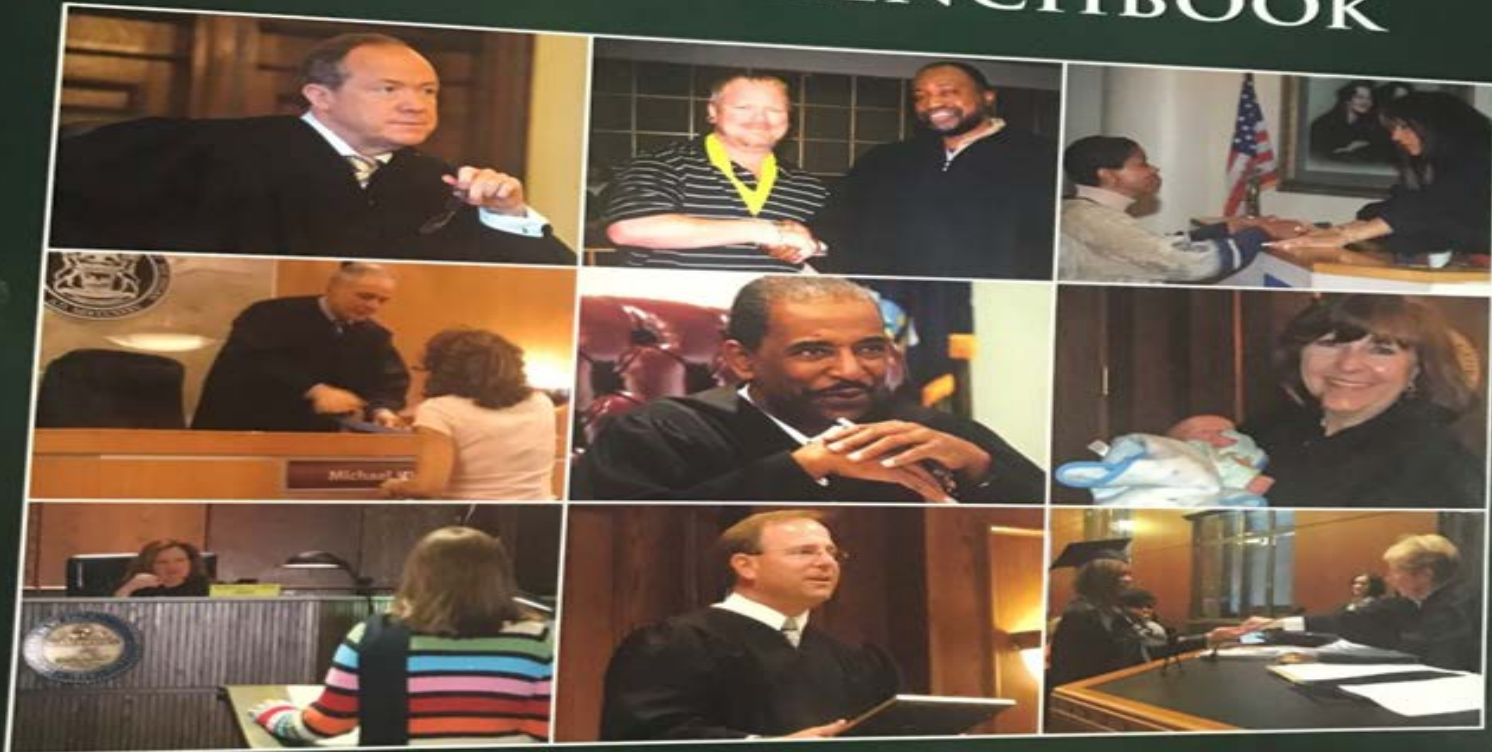
**Best Practices in the Justice
System for Addressing the
Opioid Epidemic**

JOHN P. GUN

JOURNAL

for Advancing Justice

THE DRUG COURT JUDICIAL BENCHBOOK



Edited by:
Douglas B. Marlowe, J.D., Ph.D.
Judge William Meyer (ret.)



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ONE *by* ONE

A MEMOIR OF LOVE AND
LOSS IN THE SHADOWS OF
OPIOID AMERICA





HEALING CRIMINAL JUSTICE

Judge Jeffrey Tauber

A Journey to Restore
Community in Our Courts

Ethical Considerations—The Opioid Epidemic and and The Impact on Society

Roseann B. Termini, Esq.

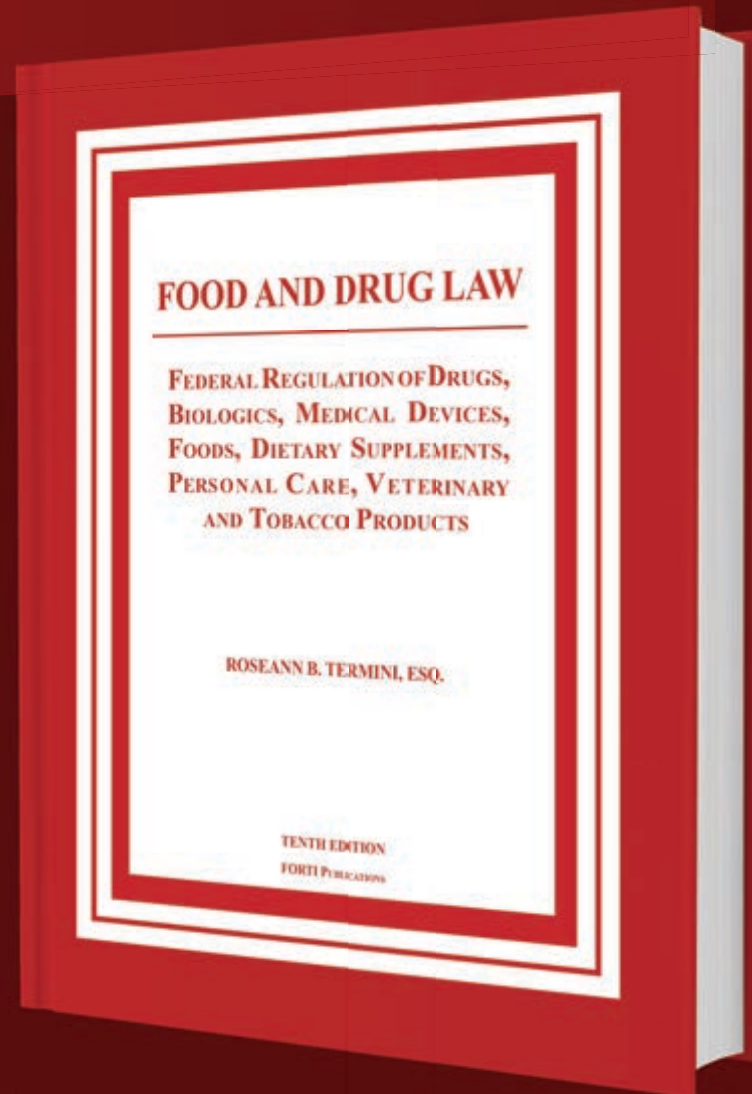
Sources

c. Roseann B. Termini, *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products Regulations* (2019) www.fortipublications.com

and

c. Roseann B. Termini and Rachel-Malloy Good, *50 Years Post Controlled Substances Act: The War on Drugs Rages on with Opioids at the Forefront* (2019).

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Rules of Professional Conduct

- 1.1. Competence
- 1.3. Diligence
- 1.4. Communication
- 2.1. Advisor
- 3.2. Expediting Litigation

Source:

<https://www.pacode.com/secure/data/204/chapter81/s81.4.html>

Ethical Considerations and Distinction

- **Is it ethical?**
- **Is it moral?**

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Attorney...

- **Advocate**
- **Problem solver**
- **And duty to.....?**

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Communication

- **What does “communication” mean in Attorney-Client Relationship?**

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Competence

- What does competence entail?
- Example: Everchanging Landscape – Opioid Litigation

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Diligence

- How does an attorney act with diligence?

Advocacy

- What does zealous advocacy mean?
- When does zealous advocacy become overzealous- Ex. MDL Motion to Disqualify
- Expediting Litigation—Settlement or Trial

Counselor

■ Advisor

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Background

Poppy Fields, Opium Dens 1875
to Synthetic Products

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Opium

Opiates – from opium

Opioids- man-made/synthetic/semi synthetic

Oxycodone (OxyContin®) Hydrocodone contains codeine (Vicodin®)

Hydromorphone- contains morphine

<https://www.drugabuse.gov/drugs-abuse/opioids>

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1950's

- Percodan (oxycodone hydrochloride and aspirin)
- Numorphan® semi synthetic (oxymorphone)

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1970s

- War on *Drugs*- *Comprehensive Drug Abuse Prevention and Control Act 1970*
- DEA 1973- diversion control

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FDA Approval

- OxyContin® – 1995 “believed to reduce likelihood of abuse”
- Moderate (chronic) to severe pain
ex. Cancer

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DEATHS From OPIOID OVERDOSE

- # varies in the U. S.
- Combined estimate from Rx and Illicit use nearly 200 Daily

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SUD

- Substance Use Disorder
- 2 million Americans related to Rx Opioid pain medication

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Victims Children

- 8 million children live with one parent who has SUD
- 35% children who enter foster care removed from home due to SUD
- Unintentional deaths-ex. opioid poisoning 9000 (1999-2016)

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Victims

Who else?

- Ex. Sex trafficking

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Opioid Crisis

- Landscape- counties, cities, towns, tribal territories, states.....
- Why? ex.–resources exhausted
- Likelihood of success

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Opioid Crisis

- Gateway to Addiction
- Example Swimmer
- Heroin- 1898 Bayer- "Heroic" ability
- Fentanyl
- Kratom

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Significant Players

- Manufacturers
- Drug Reps. Info. to Doctors-common aches and pains
- Physicians
- Dentists ex. Study 45% Opioid Rx

Big Pharma Liability

- Purdue—OxyContin (oxycodone hydrochloride) and Dilaudid (Hydromorphone)
- Endo—Percocet and Percodan
- Janssen—Duragesic and Nucynta—Tapentadol
- Teva—Actiq and Fentora—Fentanyl
- Allergan—Kadian (morphine sulfate extended-release tablets) Norco (hydrocodone and acetaminophen)

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OPIOID CRISIS EXECUTIVE LIABILITY

- ***Purdue Pharma Revisited-***
- ***Key Element- how promoted-off label promotion***

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Purdue

- **2007 Guilty Plea**
- **Fast forward 10 years later— 2017**
Federal prosecutors in Connecticut
criminal investigation about marketing.

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Role of Medical Community

- 1980 Letter to the Editor – New England J. of Medicine
- Only 4 out of 11, 882 became addicted
- Addiction rare

- <https://www.nejm.org/doi/10.1056/NEJM198001103020221>

Liability

- Distributors
- Pharmacists

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One Sided

- Ex. CEO Amerisource Bergen
- Pain reliever
- Heavily regulated

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Liability

- Rochester Company and Executives
- Distributor/Wholesaler

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Settlement

- Oklahoma \$270 million Purdue
- Oklahoma \$85 million Teva
- Resolves lawsuit filed by Oklahoma Attorney General
- Allegations deceptive marketing

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Trial

- J&J refused to settle
- \$572 million - 2019

MDL

- **MDL In re: National Prescription Opiate Litigation, case number 1:17-md-02804, in the U.S. District Court N. District Ohio**

MDL

- **Disqualification Motion Rejected U.S. Court of Appeals for the Sixth Circuit.**
https://www.sixthcircuitappellateblog.com/wp-content/uploads/sites/11/2019/09/In_Re_National_Prescription_.pdf



Settlement Framework

- Oct. 21, 2019 Announced: \$48 billion 4 state AGs Texas, Tennessee, North Carolina and Pennsylvania with Cardinal Health Inc., McKesson Corp., AmerisourceBergen Corp., Teva Pharmaceuticals and Johnson & Johnson
- <https://www.inquirer.com/business/opioids-attorneys-general-48-billion-settlement-proposal-20191021.html>

Avoiding Trial in MDL

- *County of Cuyahoga v. Purdue Pharma LP et al.*, case number 1:17-op-45004;
County of Summit et al. v. Purdue Pharma LP et al., case number 1:18-op-45090;
\$260 million settlement announced Oct. 21, 2019

Lawsuits- Insys Therapeutics

- Fentanyl Painkiller Spray—Subsys
- Promoted for any type of chronic pain
- FDA approval-cancer patients

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OPIOID CRISIS

Bankruptcy-

- Insys
- Purdue
- Drug Co. joining Purdue to End Litigation

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Former Lover

- Commonwealth of Pennsylvania v. Rebecca Delbaggio, case number MJ-24103-CR-0000097-2018
- Allegations- prescribed nearly 1,000 Oxycodone and Xanax pills to heroin-addicted lover for him to sell
- Method of repaying the \$50,000 she had loaned

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PRESIDENT TRUMP

- Declaration National Emergency

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Former FDA Commissioner Dr. Gottlieb and Acting Dr. Sharpless

- Opioid Policy Steering Committee-
- Education for doctors i.e. Only when medically necessary.
- Risk Management expanded
- Fentanyl- Mail Facilities
- “Dark Web”-agents

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DEA Opioid Crisis

- DEA – federal policy concerning manufacturing and production
- Due Process- amend regulations
- Revolving Door

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MAT

■ Medication Assisted Treatment

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Buprenorphine

- Purpose: treatment of narcotic addiction
- Suboxone® combination product with buprenorphine and naloxone
- Subutex® single entity buprenorphine
- https://www.dea.gov/diversion/usdoj.gov/drug_chem_info/buprenorphine.pdf

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Huge Issue

- Public Outrage and Outcry
- Public Officials

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OxyContin Reformulated

- Consequence - From Pills to Injections-
- Heroin and Fentanyl and Fentanyl Analogs

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Partial Fill Policy

- 2016 Federal Law- permits partial filling
- Dr. Request to Pharmacist
- Ex. 3 day-supply of 2 week prescription
- Retailer Ex. CVS

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Recent Legislation

- Cures Act
- Comprehension Addiction and Recovery Act

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Controversial Issue

- Safe Injection Sites
- Ex. Philadelphia

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Other Solutions and Outreach

- Resources
- Prevent Risk of addiction- Develop Non-Addictive Pain Meds.
- Education
- Schools
- Lifestyle Changes

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Question

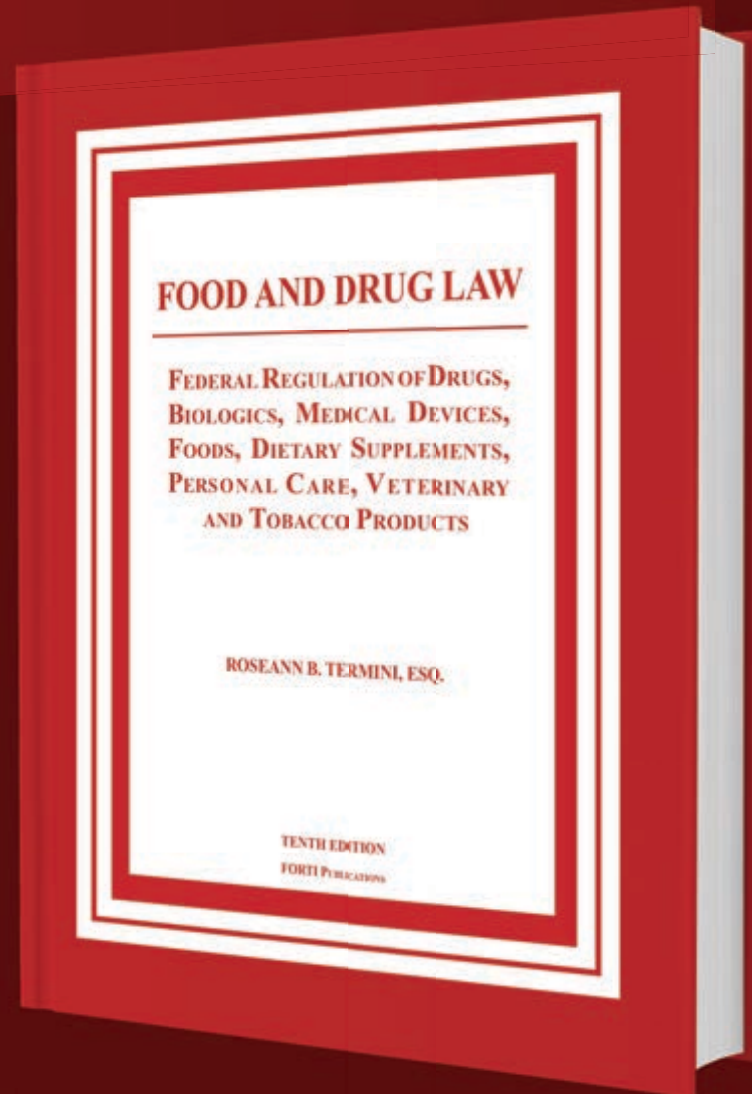
■ Quick Fix?

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Question

- The next multifaceted crisis?

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Sources

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OPIOID CRISIS

As big as any drug problem the U.S. has ever seen

THE OPIOID CRISIS AND THE BELLWETHER CASE



The New York Times

Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial

Oklahoma pursued the first case against a drug manufacturer for the national public health disaster, and the ruling may point to what lies ahead in 2,000 more lawsuits.



IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

- (1) PURDUE PHARMACEUTICALS, INC.;
- (2) PURDUE PHARMACEUTICALS, INC.;
- (3) THE PURDUE FREDERICK COMPANY;
- (4) TEVA PHARMACEUTICALS USA, INC.;
- (5) CEPHALON, INC.;
- (6) JOHNSON & JOHNSON;
- (7) JANSSEN PHARMACEUTICALS, INC.;
- (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (9) JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
- (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
- (11) WATSON LABORATORIES, INC.;
- (12) ACTAVIS LLC; and
- (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. CJ-2017-816
Judge Thad Balkman

STATE OF OKLAHOMA }
CLEVELAND COUNTY } S.S.

FILED

AUG 26 2019

In the office of the
Court Clerk MARILYN WILLIAMS

THE OPIOID CRISIS AND THE BELLWETHER CASE

The New York Times

Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial

Oklahoma pursued the first case against a drug manufacturer for the national public health disaster, and the ruling may point to what lies ahead in 2,000 more lawsuits.



- *1994-2006: Opioid sales increased 4x.*
- *2011-2015: 2,100 Oklahomans died of overdoses.*
- *2015: 326 million opioid pills sold in Oklahoma (110 pills per adult).*
- *Oklahoma dispenses most Fentanyl per capita.*
- *4.2% of babies born showed opioid withdrawal.*
- *First of its kind: What might lie ahead for 2,000+ lawsuits?*

“DANGEROUS MARKETING CAMPAIGNS”

.....



Johnson & Johnson promulgated “false, misleading and dangerous marketing campaigns” that

“caused exponentially increasing rates of addiction, overdose deaths” and babies born exposed to opioids.

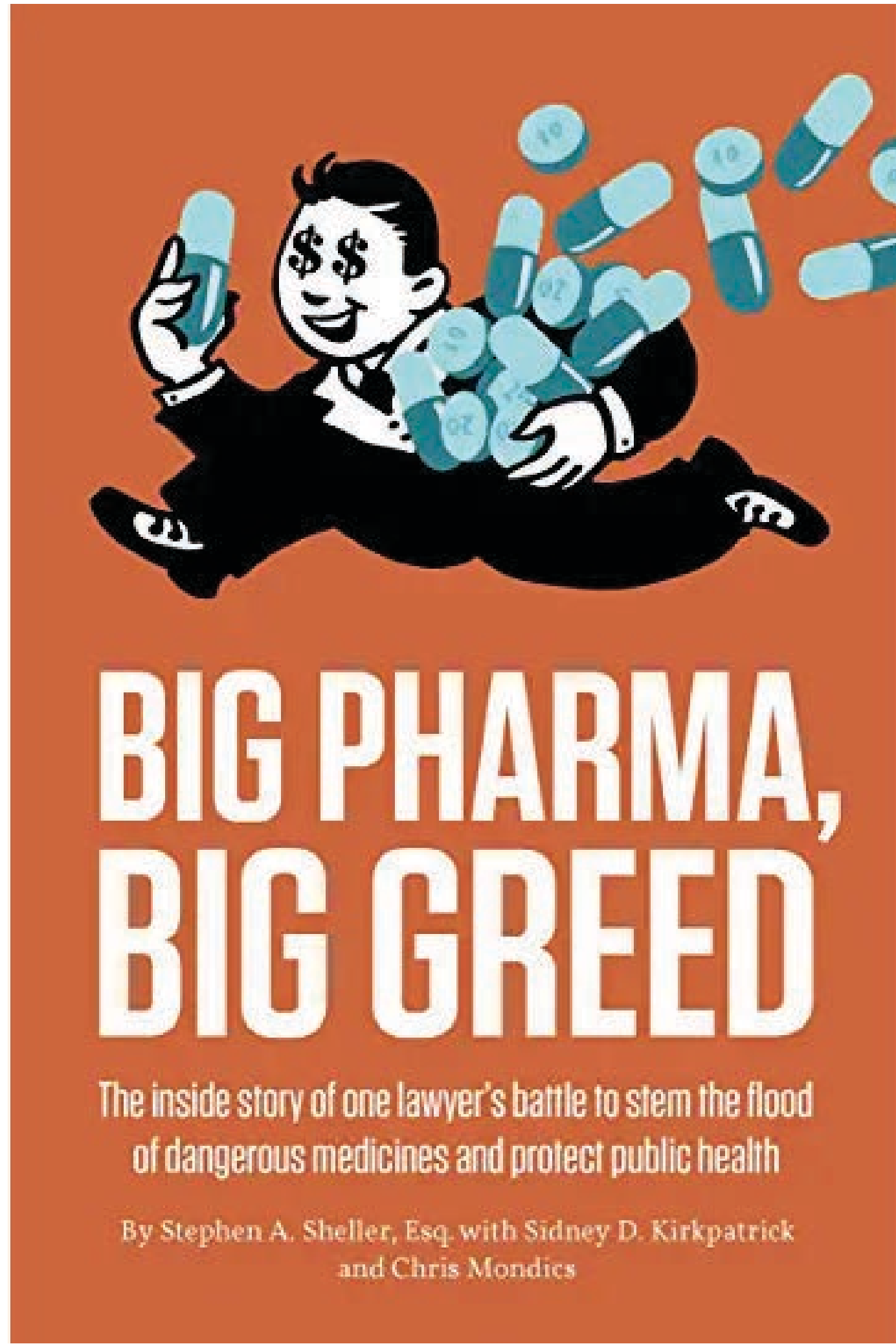
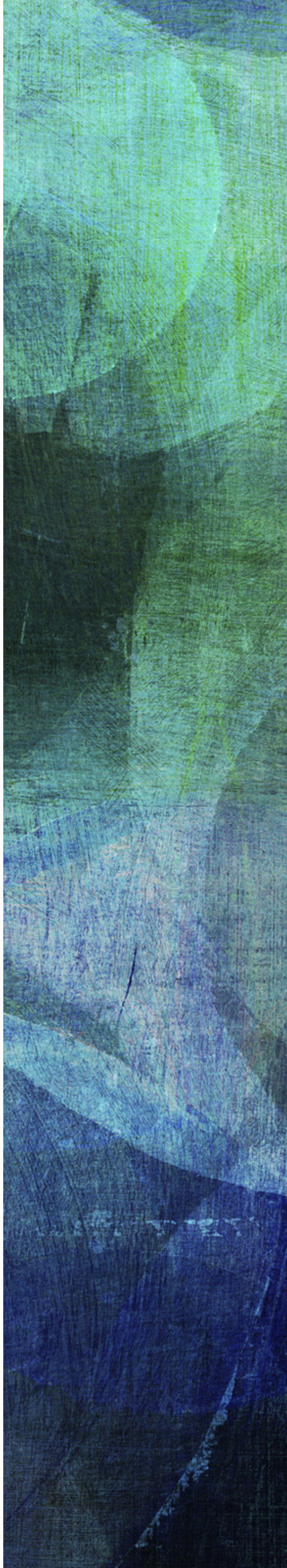
~Judge Thad Balkman

ENOUGH BLAME TO GO AROUND

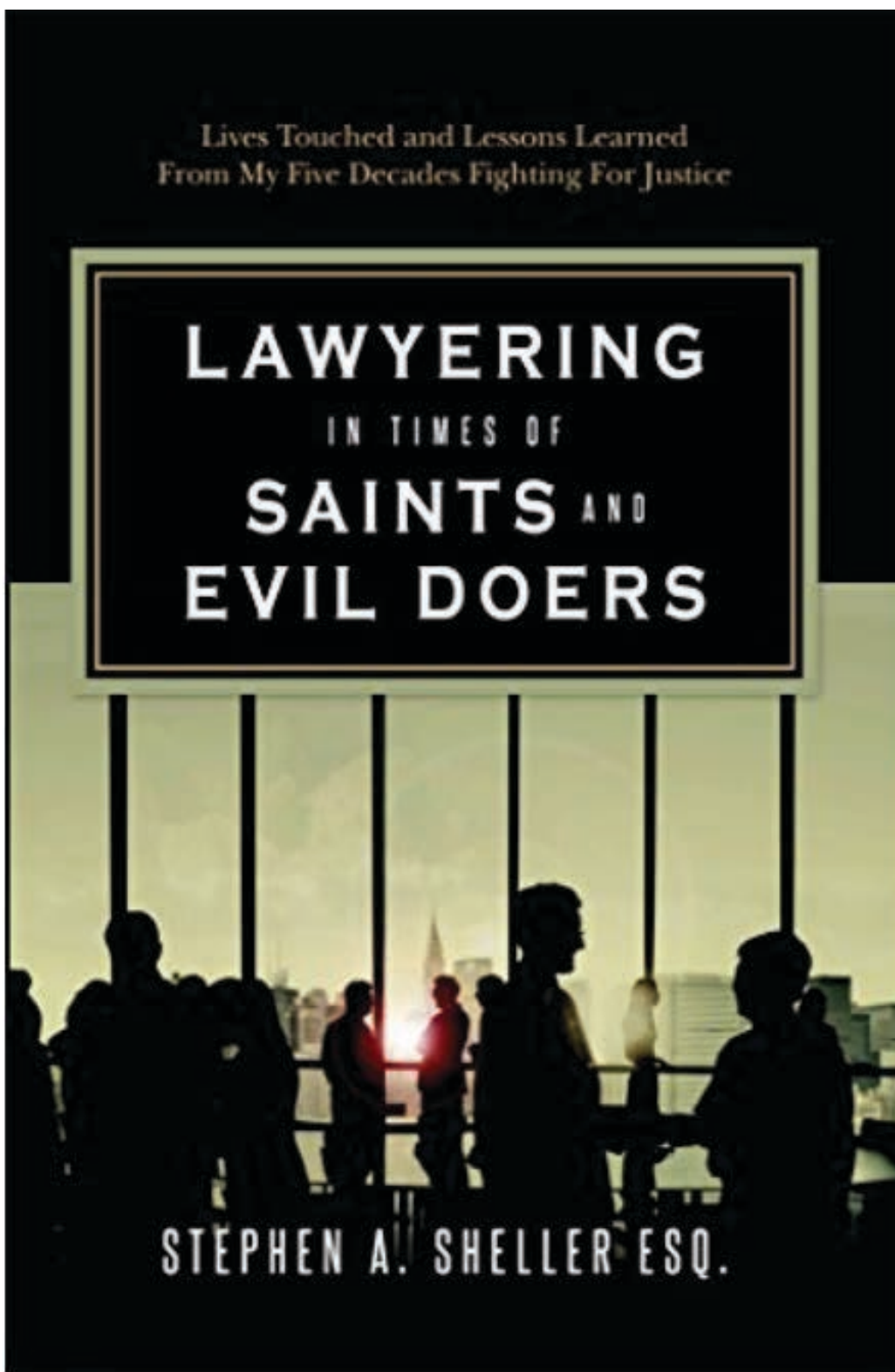


WHO'S RESPONSIBLE FOR THE OPIOID EPIDEMIC? DOCTORS OR PHARMACEUTICAL COMPANIES?

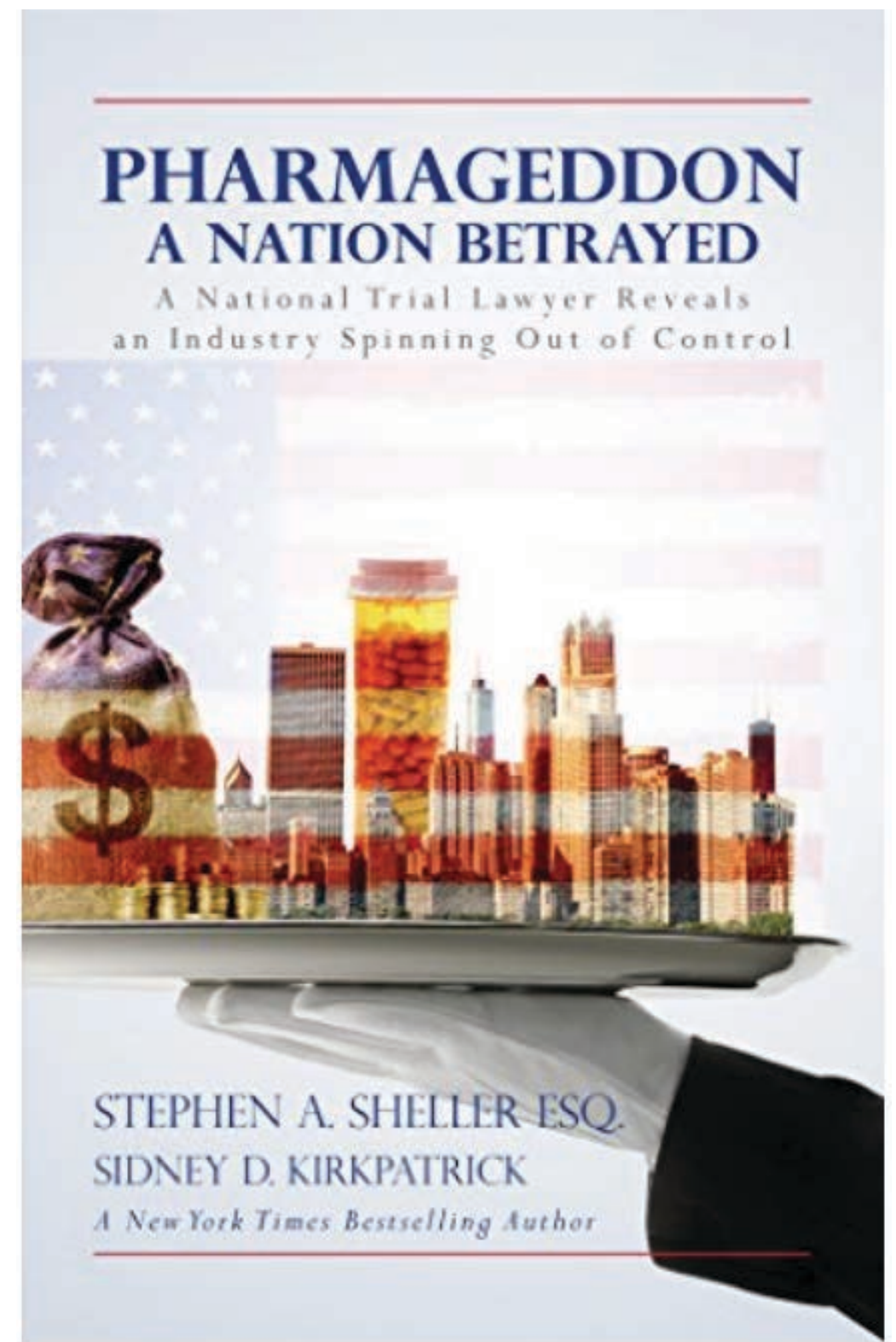
Dr. Barry Schultz is serving 157 years in prison after he prescribed enough opioids for a prosecutor to call him one of Florida's "most notorious drug dealers." In this "60 Minutes" interview, Schultz says he's a scapegoat



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