Combatting the Opioid Epidemic:

Update on the Nationwide Litigation



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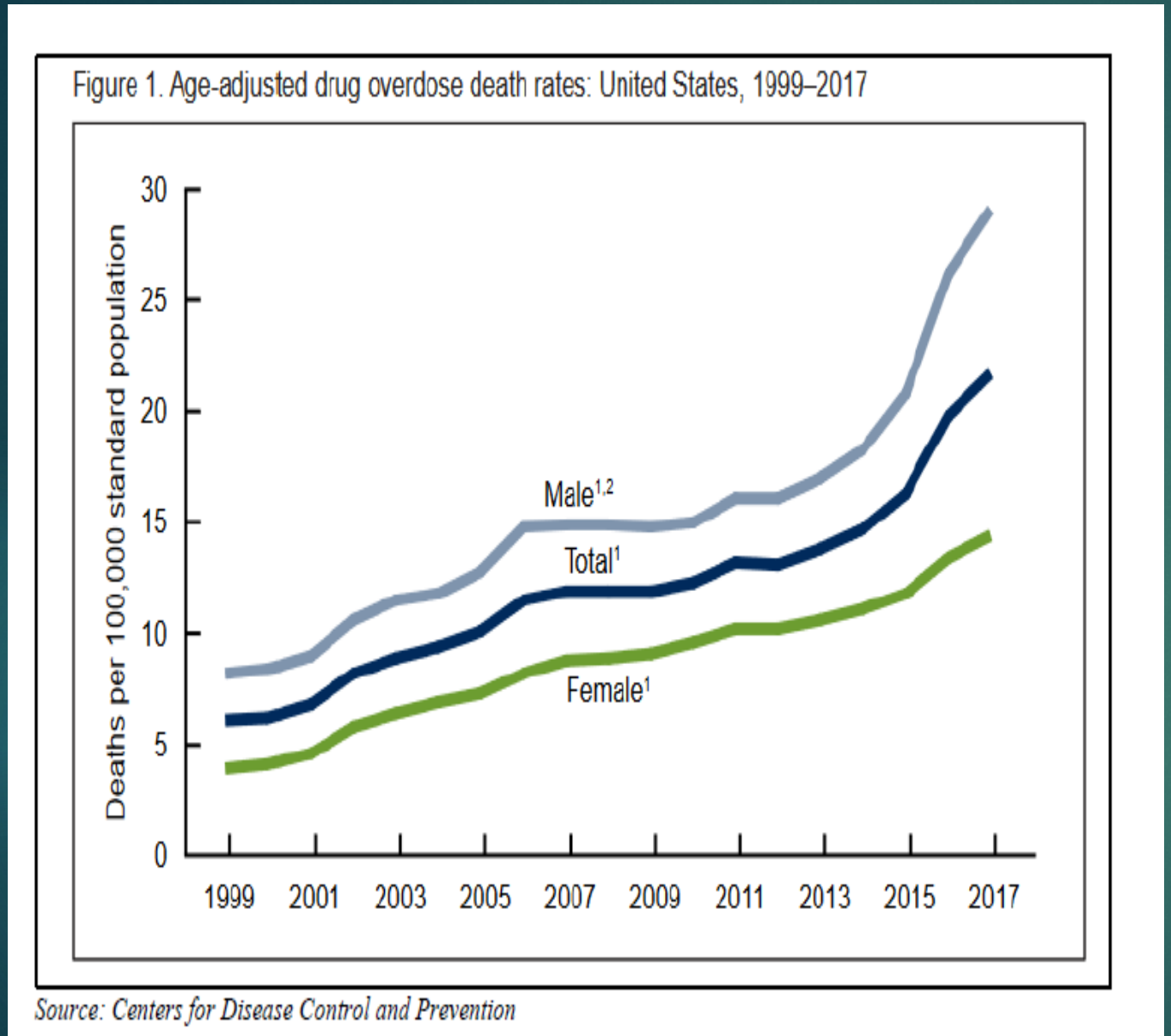
How the Litigation Started….

An Opioid Epidemic

- By 2013, 1 in 20 people in the U.S. reported using prescription opioids non-medically in the past year;
- By 2013, More than 45 people were dying per Day in this country from prescription opioids;
- Each year from 1999 to 2010 that death toll rose (from 4,030 in 1999 to 16,651 in 2010 alone);
- In 2018, nearly 47,000 Americans died as a result of an opioid overdose;
- From 1999–2018, almost 450,000 people died from an overdose involving any opioid, including prescription and illicit opioids.



The death toll from opioids has continued to rise:

Opioids have actually caused life expectancy in the U.S. to decrease

- In 2017, the CDC announced that the United States life expectancy had actually declined in the last several years, due to the increase in drug overdose deaths
- "The latest CDC data show that the U.S. life expectancy has declined over the past few years. Tragically, this troubling trend is largely driven by deaths from drug overdose and suicide. Life expectancy gives us a snapshot of the Nation's overall health and these sobering statistics are a wakeup call that we are losing too many Americans, too early and too often, to conditions that are preventable."

Death is not the only consequence: Addiction

By 2017:

- 2,110,000 people suffered from OUD
- 11,401,000 used opioids for nonmedical uses

Addiction Causes a Host of Societal Consequences

- Increasing use of heroin and fentanyl;
- Increasing rates of injection-related infectious diseases;
- Negative impact on the work force;
- Soaring increases in neonatal abstinence syndrome;
- Dramatic increase in children entering foster care system

The Effect on Local Governments

- Health and Human Services
- Child Welfare
- Out of Home Placements
- Human Resources
- Office of the Sheriff/County Jail
- Justice System
- Hospitals and Nursing Homes

What Caused the Epidemic?

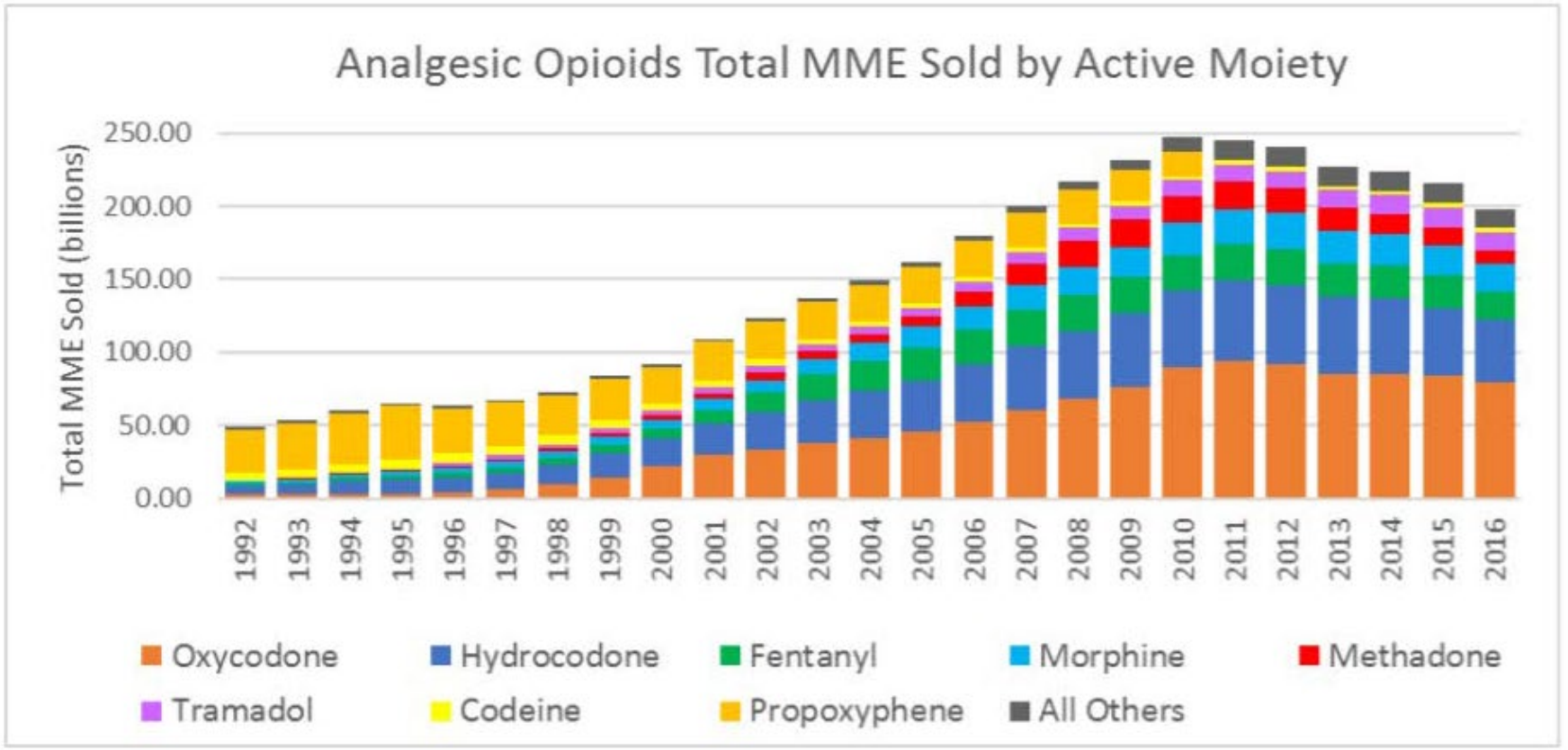
Investigation Revealed

- The Opioid Industry normalized wide-spread use of opioids:
  - Campaign of misinformation directed to medical community
  - Ignoring Controlled Substance Act duties
  - Supplied a tidal wave of dangerous narcotics to every corner of the United States
  - Supply was far beyond any legitimate medical purpose

Opioids were supposed to be drugs that were used sparingly and kept in a closed system –that is not what happened…..

A tsunami of pills flooded the United States….

Figure 2: Total MMEs sold for aggregate opioid analgesic market – by active moiety



Deaths mirrored Sales….

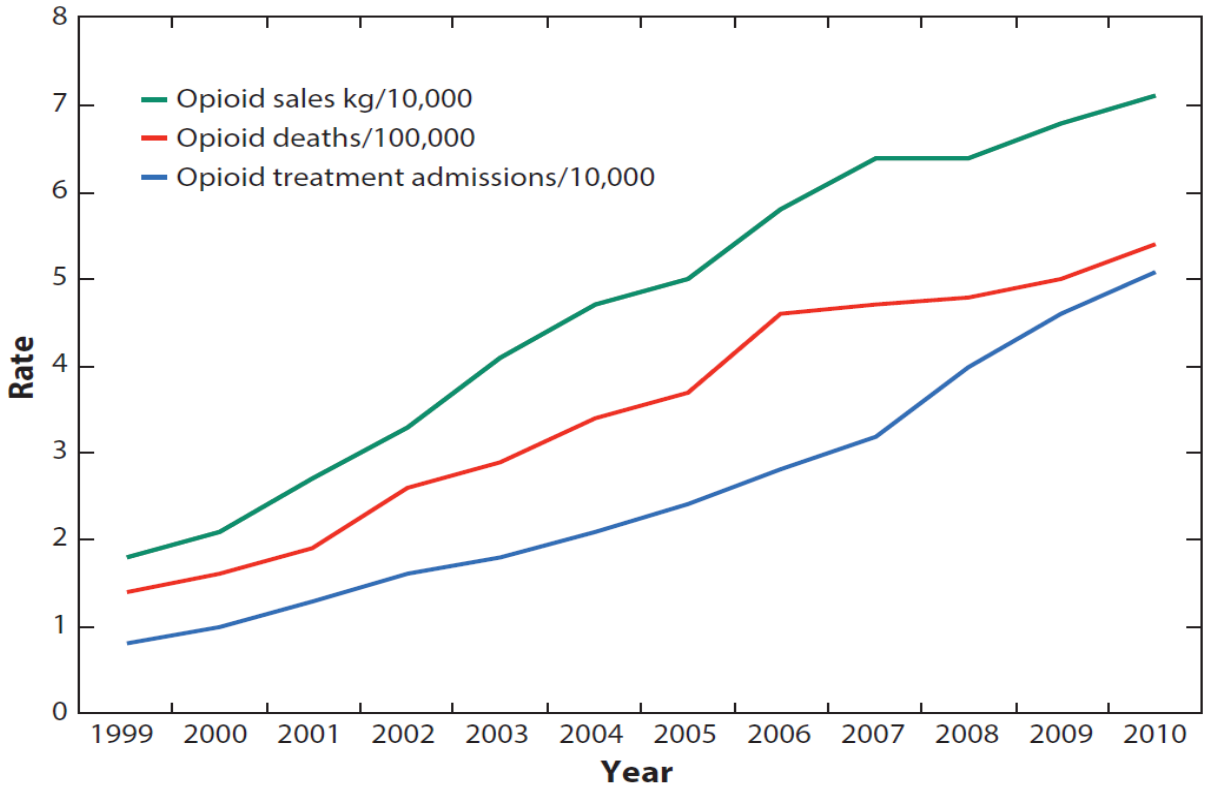


Figure 1

Rates of OPR sales, OPR-related unintentional overdose deaths, and OPR addiction treatment admissions, 1999–2010. Abbreviation: OPR, opioid pain reliever. Source: 10.

Who Was Responsible?
The Opioid Supply Chain

Manufacturing Defendants

- Purdue
- Janssen Pharmaceuticals / J&J
- Mallinckrodt / SpecGX
- Actavis / Allergan / Watson Pharmaceuticals
- Teva / Cephalon
- Endo
- Insys

Distributor Defendants

- McKesson Corporation
- AmerisourceBergen Drug Corporation
- Cardinal Health Inc.

Retail Pharmacy Defendants

- Walmart
- Walgreens
- CVS
- Rite-Aid
- Regional pharmacy chains

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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

THE COUNTY OF SUFFOLK,

Plaintiff,

v.

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. N/K/A JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; RUSSELL PORTENOY; PERRY FINE; SCOTT FISHMAN; and LYNN WEBSTER,

Defendants.

Index No.

COMPLAINT

Local Governments Decided to Fight Back

Counties Started Filing Lawsuits

- Suing the Opioid Industry:
  - Manufacturers
  - Distributors
  - Chain Pharmacies

Marketing Conduct

- Advertising in medical journals: aura of legitimacy
- Key Opinion Leaders: national experts
- Conference sessions: continuing medical education
- Local influencers: paid to attend
- Off-label promotions: beyond FDA-approved statements
- “Pseudo-addiction”: withdrawal requires greater doses

Distribution Conduct

- Failed to have any adequate system in place to check oversupply and diversion
- Ignored red flags for oversupply and diversion
- Failed to meet obligations under the Controlled Substances Act
- Participated in the false marketing and normalization of wide-spread opioid use

Causes of Action

- Deceptive Acts and Practices
- False Advertising
- Public Nuisance
- Violation of Social Services Law
- Fraud
- Unjust Enrichment
- False Claims
- Conspiracy/RICO

Causes of Action

- Under the Federal Controlled Substances Act ("CSA"), distributors are required to report suspicious orders of controlled substances like Opioids.
- Distributors also have tools to track surges in demand, even at the level of individual pharmacies and clinics.

Litigation Goals

- **ACCOUNTABILITY**
- **MONETARY RELIEF**
- **ABATEMENT OF THE EPIDEMIC**

Practically Speaking – The Main Cause of Action

Public Nuisance

This has been the claim that best addresses the Defendants' conduct.

A ***public nuisance*** is an act or condition that unlawfully operates to hurt or inconvenience an indefinite number of persons. In other words, a public nuisance affects the general public. The definition of a public nuisance is consistent with the RESTATEMENT (SECOND) OF TORTS § 821B(1), which defines a public nuisance as "an unreasonable interference with a right common to the general public.'" Circumstances that may sustain a holding that an interference with a public right is unreasonable include the following:

(a) Whether the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience, or

(b) whether the conduct is proscribed by a statute, ordinance or administrative regulation, or

(c) whether the conduct is of a continuing nature or has produced a permanent or long-lasting effect, and, as the actor knows or has reason to know, has a significant effect upon the public right.

Most Cases have been Narrowed by Plaintiffs By Choice

Public Nuisance is the lead Cause of Action that is Proceeding to Trial Around the Country

In the Beginning

- The multi-district litigation ("MDL"), or nationwide litigation on behalf of counties and cities, began in January 2018 (nearly two years ago)
- At that time, several hundred counties had sued manufacturers and distributors of prescription opioids
- A handful of states had filed suit, mostly against Purdue Pharma

Where Are We Today – September 2020

- Over 2600 County and City Governments Filed Suit vs. 28 Defendants including manufacturers, distributors and pharmacy chains.
- Many states have filed cases and all states have been in some form of organized negotiations with Defendants.

The Multi-District Litigation

- Cases were consolidated in early 2018
- Court put cases on a fast track to the first trial (originally 12 months to trial - moved to 18 months)
- Discovery proceeded against 28 Defendants simultaneously

The Multi-District Litigation

- Over 160 million pages of documents were produced
- Over 400 depositions were taken in a three-month period
- Over 300 Third Party Subpeonas issued
- Over 2600 Requests for Production, Interrogatories and 30(b)(6) Topics issued
- 11,000 pages of written discovery responses
- Plaintiffs hired 28 experts, disclosed lengthy reports and prepared and produced experts for deposition over just three short weeks.

The Multi-District Litigation

Defendants disclosed 74 expert witnesses.

MDL counsel deposed those experts over a period of four weeks.

On June 28, 2019 - Defendants filed 28 Motions for Summary Judgment asking the Court to dismiss Plaintiffs' claims and 14 motions challenging Plaintiffs' expert witnesses and 104 Motions in Limine prior to trial

Plaintiffs responded to this slew of motions in hundreds of pages of briefing.

September 2019 - Court Denies nearly all Defendants' Motions (including motions to dismiss Plaintiffs' case on causation, Plaintiffs' RICO and Conspiracy claims and nearly all of Defendants' challenges to Plaintiffs' Expert Witnesses)- sends the First Case for Trial in Cleveland, Ohio.

The Multi-District Litigation

- Prior to the First MDL Trial- Court severs out certain Defendants including (the pharmacy chain Defendants except for Walgreens and a group of minor distributors)
- A select group of Defendants head to Trial starting October 21, 2019 including:
  - The manufacturers (except for Purdue who declares bankruptcy in September before trial)
  - The Big Three Distributors (McKesson, Amerisource Bergen, Cardinal Health)
  - Walgreens
  - Henry Schein (minor distributor Defendant)
- The Court's view was that trial against 28 Defendants was unmanageable & a relatively discrete case needed to proceed to trial.

In the Meantime… the State of Oklahoma went to trial vs. Janssen

- Oklahoma, August 2019
- J&J created a public nuisance by aggressively pushing drugs to doctors
- 42-page Judgment
- J&J ordered to pay $465 million

MDL: First Trial

- Settled in the early morning hours before trial on October 21, 2019 for approximately $260 Million to the two Ohio Counties set for trial.

What Happened Next?

MDL Court Selects 6 Additional "Bellwether" Cases for Trial

- West Virginia – Cabell County & City of Huntington (CT2): October 19, 2020 – Big Three Distributors Only
- N.D. Ohio – Summit & Cuyahoga Counties (CT1B): November 9, 2020 – Pharmacy Chain Defendants- Distribution only claims
- N.D. Ohio – Lake & Trumball Counties (CT3): May 10, 2021
- City of Chicago – Manufacturers Only (not the bankruptcy Defendants Purdue & Insys)
- City and County of San Francisco – All Remaining Defendants & All Claims
- Oklahoma - Cherokee Nation

Purpose of New Set of "Bellwether" Cases

- Put pressure on the Defendants on differing fronts.
- Trials increase pressure on Defendants. The more cases are trial ready the more pressure is exerted.
- Focused cases put more pressure on that group of Defendants.
- Ultimate Goal = Drive a global resolution.

Next Trial: October 19, 2020

October 19, 2020 in Charleston West Virginia

Plaintiffs are Cabell County, WVA and the City of Huntington, WVA

Defendants are the "Big Three" Distributors- Cardinal, McKesson and Amerisource Bergen

Sole Cause of Action: Public Nuisance

Status of Global Settlement Discussions:

No Resolution has been reached	Talks have been ongoing in earnest	Bankruptcies have occurred:
		• Purdue Pharma • Insys

Where Does the Negotiation Class Stand?

What is the Negotiation Class?

The Negotiation Class was created as a vehicle that could be used to negotiate with Defendants on behalf of all local governments collectively.

It was meant as a vehicle to bind all who didn't opt out of the class.

Plaintiffs argued would allow Defendants to buy peace with all local governments at one time.

Defendants did not have to use this vehicle.

The Opt-Out Option

- The Negotiation Class is a voluntary class. Counties could opt-out under a schedule set by the Court – November 22, 2019 Deadline.
- Counties who did not affirmatively opt out by that deadline are in the Class.
- Those who opted out do not vote on any proposed settlement where the Class vehicle is used.
- Class members do vote and would share in any approved settlement.

Have Defendants Taken Advantage of the Negotiating Class?

- Not to date.
- However - the formula may be used to determine allocation as between counties and cities if a settlement is reached.

Purdue Bankruptcy



Purdue Statement Pre-Bankruptcy

The Cases had not settled…



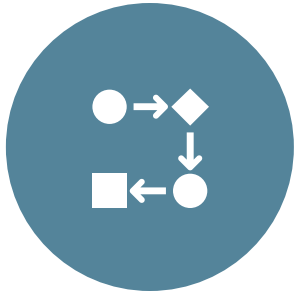
No claims against Purdue are resolved.



When Purdue went into bankruptcy its ability to "settle" claims will now be run by the bankruptcy court and administered through that court.



The Court has held a number of hearings to try to set a plan for how to apportion Purdue's assets among the various creditors and claimants.



That process is not complete and is ongoing.

Relevant Deadlines in the Bankruptcy Proceeding

- Abatement Plan Term Sheet, June 4, 2020
- Proof of Claims submitted: July 30, 2020

Bankruptcy Proceedings

- The $10 billion proposed settlement plan calls for the Sackler family to hand over Purdue to a trust controlled by the states, cities and counties that have sued to recoup billions spent battling opioid addictions and overdoses.
- It also would require the family to come up with $3 billion themselves.

Resolution will continue to work its way through the bankruptcy court

What is Next on the Horizon?

Settlement Efforts Continue….

Remains to be seen whether a global resolution will occur and with which Defendants.

Settlements will likely occur in pieces with individual Defendants or groups of Defendants.

An Ongoing Issue

Interstate Allocation Agreements

How the dollars would flow in a geographic state as between the State, the Counties and the Cities

Strong Recommendation: Get an Agreement in place

Discussions are ongoing between AGs and Local Governments in nearly every state

Interstate Allocation Negotiations

Three States have signed Allocation Agreements (Ohio, Texas, and New York)

Counties and the AG Should be Discussing What Allocation Would Look Like in Your Particular State

There is Still a Lot to Do ….



TO GET TO A SUCCESSFUL CONCLUSION…



YOUR PARTICIPATION WILL BE CRITICAL

QUESTIONS?

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