Opioid Settlements

WHOLESALE DRUG DISTRIBUTORS AND JANSSEN
By 2017, over 2,000 federal lawsuits had been filed by government entities against opioid-related defendants. Among those defendants were opioid distributors and manufacturers.

In 2017, a federal judicial panel consolidated these cases into multidistrict litigation (MDL).

- The MDL was consolidated under one judge in the Northern District of Ohio.

In 2019, after receiving pressure from the MDL judge, three of the nation’s largest drug distributors—McKesson, Cardinal Health, and AmerisourceBergen—agreed to settlements. Janssen, an opioid manufacturer, also agreed to settlement.

In 2021, the details of the settlement were released.
Who is settling?

Three of the Nation’s largest wholesale drug distributors: McKesson, Cardinal Health, and AmerisourceBergen
- This includes several thousand subsidiaries of these companies.

Opioid manufacturer Janssen, a subsidiary of Johnson and Johnson.
What is being settled?

Many governments have agreed to release certain legal claims against these defendants, related to opioids. In exchange for government’s releasing those claims, the defendants have agreed to do certain things and pay money.

- Doing certain things is known as injunctive relief.
- Paying money is known as monetary payments.
What do the defendants have to do?

Janssen (Opioid Manufacturer), for 10 years, has agreed to:

- Stop selling and manufacturing opioids
- Stop promoting opioids
- Stop providing financial incentives to sales teams for opioid sales
- Stop lobbying for federal, state, local, and regulatory provisions that encourage or require health care providers to prescribe opioids
- Stop lobbying against federal, state, local, and regulatory provisions that
  - Support non-opioid pain relief
  - Prescribing the lowest effective dose
  - Prescribing naloxone and using urine testing for those with opioid prescriptions
  - Support evidence-based treatments (like MAT)
What do the defendants have to do?

The Distributors have agreed, for a period of 10 years, to:

- Create and implement a Controlled Substance Monitoring Program (CSMP)
  - CSMP is responsible for onboarding and approval of new controlled substance pharmacies, setting and adjusting pharmacy thresholds, terminating or suspending pharmacies, and identifying red flags.
  - CSMP must conduct ongoing due diligence and conduct site visits, among other things.

- Create and implement a National Clearinghouse to receive and analyze data received from this injunctive relief.
  - The Clearinghouse will allow Distributors to obtain comprehensive data from other Distributors, pharmacies, and other relevant sources.
  - States will have access to the data to query without limitation.
What do the defendants have to pay?

The Distributors and Janssen will pay up to $26 billion nationwide.

Michigan will receive up to 3.4%, or approximately $776 million over the course of 18 or less payments.

Payments are unlikely to be the same from year to year because of certain options in the settlement agreement.

Participation of States and eligible local governments is key.

Michigan is a participating state and 269 of 278 eligible local subdivisions participated in the settlements.
**DISTRIBUTORS: Base and Incentives**

<table>
<thead>
<tr>
<th>Incentive</th>
<th>Description</th>
<th>Participation Sliding Scale (Incentive B)</th>
<th>Incentive C Sliding Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incentive A</strong></td>
<td>Provides for payment of all but Incentive D payments in exchange for near full peace.</td>
<td>85%: 30% 86-90%: 40% 91-94%: 50% 95-99%: 60% 100%: 100%</td>
<td>Not structured in time periods, as with Incentive B under the J&amp;J Agreement.</td>
</tr>
<tr>
<td><strong>Incentive B</strong></td>
<td>Not relevant if a State earns Incentive A.</td>
<td>Participation, Release, or Resolution Levels: 60-69%: 25% 70-74%: 35% 75-79%: 40% 80-84%: 45% 85-89%: 55% 90-92%: 60% 93%: 65% 94%: 75% 95-97%: 90% 98-99%: 95% 100%: 100%</td>
<td>There is no timing element.</td>
</tr>
<tr>
<td><strong>Incentive C</strong></td>
<td>Not relevant if a State earns Incentive A.</td>
<td>Participation, Release, or Resolution Levels: 60-69%: 25% 70-74%: 35% 75-79%: 40% 80-84%: 45% 85-89%: 55% 90-92%: 60% 93%: 65% 94%: 75% 95-97%: 90% 98-99%: 95% 100%: 100%</td>
<td>There is no timing element.</td>
</tr>
</tbody>
</table>

**Incentive D**
- 5% share of the State’s total Abatement Fund allocation (see page 20). Payable starting in year 6 through year 18.
- Qualifying Criteria: State must have had no later Litigating Subdivisions bring suit and proceed past preliminary motions.

**Base 55% Incentives 45% Net Abatement Amount**
- Incentives are earned by obtaining releases from subdivisions and limiting additional subdivisions from filing suit.
- During the first two years, States that settle are treated as if receiving full base and incentive.

Illustrative only- Executed Agreements Control.
### Incentive A

Incentive A provides for payment of all but Incentive D payments in exchange for near full peace. Earning Incentive A also causes substantial payments, the first three years of payments, accelerated and paid within 90 days.

Incentive A is earned by:
- Passing a Statute or court ruling that terminates existing and bars future claims by subdivisions (including special districts);
- Receiving releases on behalf of (i) all general purpose subdivisions above 10,000 population, (ii) larger school and hospital/health districts, and (iii) all currently litigating subdivisions; or
- A combination of these approaches that results in a complete bar of existing and future claims (e.g., legislation barring future claims combined with 100% participation by litigating subdivisions).

### Incentive B

- Incentive B is not relevant if a State earns Incentive A.
- Incentive B is up to 30%.
- Incentive B is earned from obtaining releases from litigating subdivisions.

**Incentive B Sliding Scale:**

<table>
<thead>
<tr>
<th>Participation or Case-Specific Resolution Levels</th>
<th>Incentive B Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td>76%</td>
<td>52%</td>
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<tr>
<td>77%</td>
<td>54%</td>
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<td>78%</td>
<td>56%</td>
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<td>79%</td>
<td>58%</td>
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<tr>
<td>80%</td>
<td>60%</td>
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<tr>
<td>85%</td>
<td>70%</td>
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<tr>
<td>90%</td>
<td>80%</td>
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<tr>
<td>95%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### Incentive C

- Incentive C is not relevant if a State earns Incentive A.
- Incentive C is up to 20%. It breaks Incentive C in two parts.
- Incentive C is earned by getting larger (population of 30,000) litigating and non-litigating counties and cities to join the deal. 5% is awarded for obtaining a State’s ten largest general purpose subdivisions (cities and counties).

**Incentive C Sliding Scale:**

<table>
<thead>
<tr>
<th>Participation, Release, or Resolution Levels</th>
<th>Incentive C(1) Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>70%</td>
<td>45%</td>
</tr>
<tr>
<td>80%</td>
<td>50%</td>
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<tr>
<td>85%</td>
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<td>92%</td>
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<td>93%</td>
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<td>94%</td>
<td>90%</td>
</tr>
<tr>
<td>95%</td>
<td>100%</td>
</tr>
</tbody>
</table>

There is no timing element.

### Incentive D

5% share of the State’s total Abatement Fund allocation (see page 20). Payable starting in year 6 through year 18.

#### Qualifying Criteria

- State must have had no later Litigating Subdivisions bring suit and proceed past preliminary motions in the 5 years following the Effective Date.
Implementation

**STEP 1**
State Attorneys General have 30 days to decide to participate and give notice to the Settling Defendants (SD). SD will have up to 14 days to accept as Critical Mass of States.

**STEP 2**
- **YES**
  - Litigating Subdivisions have 120 days to decide to become Initial Participating Subdivisions.
- **NO**
  - Deal fails and litigation continues.

**STEP 3**
- **YES**
  - When final, file Consent Judgment in each participating state.
- **NO**
  - Continuing effort to get participation by all Litigating and Non-Litigating Subdivisions in order to earn Incentive A.

*Sole discretion of Distributors & J&J*

2021.07.22 Subject to Update & Correction/Executed Agreements Control
Michigan State-Subdivision Agreement
Available at Michigan.gov/agopioids

- Controls the allocation of funds to the State and Local Subdivisions, instead of what is listed in Master Settlement Agreement.
  - Allocates 50% to Local Subdivisions and 50% to the State. This is instead of 15% to Local Subdivisions, 15% to the State, and 70% to a fund.
  - Deductions for an Administrative Fund, Litigating Local Government Attorney Fee Fund, and Special Circumstance Fund.

- Allocations to individual local subdivisions are determined by a nationally used formula, modified by a litigation adjustment.

- Individual local subdivisions with an allocation percentage of less than .0023% (approx. $7,500 or less in total) will receive their complete recovery in the first payment.

- Local subdivisions may voluntarily assign all or part of their allocation to another participating subdivision.
Michigan State-Subdivision Agreement
Available at Michigan.gov/agopioids

- Attorney fees are limited to 15% of an individual Litigating Local Government’s recovery and offset by a National Fee Fund.
  
  - For example, Subdivision A contracted with Attorney X for a 30% contingency fee. Attorney X’s fee is limited to 15% of Subdivision A’s recovery by the Michigan State-Subdivision Agreement and by order of the Court. The National Fee Fund pays 7% and the remainder is paid by the Litigating Local Government Attorney Fee Fund. Fees are paid over the course of 7 years.

- Special Circumstance Fund: Local subdivisions may apply for additional funding for any local impact that is not captured by a Local Government’s allocation percentage.

  - The application deadline is March 30, 2022, but there is active effort to move this date back because everything is taking longer than expected.
How may settlement funds be used?

Governed by “opioid remediation” as defined in the Distributor and Janssen Settlements; Guided by “Exhibit E” of the Distributor and Janssen Settlements

- Opioid Use Disorder (OUD) Treatment
- Treatment and Recovery Support
- Connecting People to Help
- Address Needs of Criminal Justice-Involved Persons
How may settlement funds be used?

Continued

- Address Needs of **Pregnant Women, Infants, and Parents**
- **Prevention**
- First Responder **Support**
- **Leadership** Planning
- **Training**
- **Research**
When will payments begin?

Payment #1
as early as
April 2022

Payment #2
as early as
July 2022

Subsequent payments will be received annually in July.
KEY PRINCIPLES

Settlement funding planning will follow three key principles identified by the state:

1. Align settlement funding with the State of Michigan Opioid Strategy
2. Address systemic barriers to services
3. Provide equitable distribution of funding
State of Michigan Opioids Strategy

**Prevention**
- Educate the public
- Promote prescribing best practices
- Address unlawful supply
- Streamline treatment access & improve post overdose care

**Treatment**
- Support long term recovery
- Increase treatment capacity, especially for MOUDs
- Expand access to recovery housing

**Recovery**
- Support recovery friendly workplaces
- Expand access to recovery housing
- Support connections to services that address social determinants of health

**Harm Reduction**
- Expand & target naloxone distribution
- Expand syringe service programs in high-need communities

**Criminal-Legal**
- Expand MOUD in prisons, jails & courts
- Increase treatment access
- Expand diversion activities

**Pregnant & Parenting**
- Increase SUD screenings in prenatal care
- Improve care for pregnant women with SUD & infants with NAS

**Data**
- Establish coordinated data strategy
- Use & share data to inform response

**Equity**
- Address disparities in treatment access
PREVENTION

- Launching targeted media campaigns
- Supporting and promoting prescription drug takeback events
- Supporting local prevention coalitions
- Supporting quick response teams following a nonfatal overdose
Increased Treatment Capacity

- Michigan Opioid Collaborative (MOC) – provide technical assistance and support to buprenorphine prescribers – ongoing
- Emergency department MOUD – Partnering with Michigan Opioid Partnership to expand medications for opioid use disorder (MOUD) in emergency departments across the state – ongoing

Reducing Administrative Barriers

- Removed Medicaid prior authorization for buprenorphine – Late 2019
- Updated Medicaid Reimbursement Policy for Office Based Opioid Treatment - 2021
- Received federal approval to change Essential Health Benefits Plan to expand access to treatment and naloxone in public and private health insurance – 2020
- **OUD/SUD Treatment Costs, Case Management, and Transportation** - covers costs for individuals with SUD/OUD to access treatment, transportation to treatment, and offers case management to individuals – ongoing

- **Peers in emergency departments, outpatient treatment, and community settings** - integrates peer support specialists in different treatment settings – ongoing

- **Recovery Housing** - cover recovery housing costs for individuals with SUD/OUD – ongoing

- **Certification of Recovery Residences** - Certify recovery residences in Michigan according to National Association of Recovery Residence standards – ongoing
HARM REDUCTION

- Promoting naloxone distribution in key locations & expand scope of standing order
  - Naloxone portal has bulk orders of naloxone throughout Michigan
- Promoting adoption of EMS leave behind programs & require licensed EMS vehicles be equipped with naloxone
- Expanding SSPs and increase service delivery in communities of need
  - 81 locations operating in Michigan
- Conducting street outreach in high-need communities
CRIMINAL-LEGAL

- Supporting MOUD use in treatment courts, through technical assistance, education, & funding
- Supporting training for judges, prosecutors, and defense counsel on science of addiction, MOUDs, and ADA requirements
- Streamlining Medicaid re-activation for eligible individuals leaving prisons or jails; provide access to CC360
- Establishing data sharing procedures between Medicaid and county jails
- Expanding the Angels Program and explore additional opportunities for diversion from criminal-legal system to treatment
- Providing funding through the PIHPs to expand jail-based access to MOUD and prison access to MAT
- Michigan Department of Corrections (MDOC) oversees all state prisons
- County sheriffs oversee local jails
PREGNANT AND PARENTING WOMEN INITIATIVES

Rooming-In for Infants with Neonatal Abstinence Syndrome (NAS)
- War Memorial Hospital in Sault Ste. Marie, Hurley Medical Center in Flint, and Munson Medical Center in Traverse City received funding to retrofit space for rooming-in care

High Touch, High Tech (HT2)
- HT2 project uses a tablet-administered app to screen pregnant women for mental health and substance use disorders and connect them to treatment

Michigan awarded State Pilot Grant Program for Treatment of Postpartum Women (PPW-PLT)
- Grant provides up to $900,000/yr. for three years to PIHP Region 2 and Region 7 to support P/PW with a primary SUD diagnosis as well as direct additional funding to HT2 project
In 2020, overdose data showed alarming racial disparities:

- The opioid overdose death rate for Black residents, increased from 29.1 deaths per 100,000 in 2019 to 37.5 deaths per 100,000 in 2020.
- The opioid overdose death rate for Hispanic residents, increased from 15 deaths per 100,000 in 2019 to 22.3 deaths per 100,000 in 2020.
- Michigan Opioid Task Force set to launch a Racial Equity Workgroup to address these disparities.
  - Support culturally competent community outreach in majority-minority communities
  - Promote MOUD in majority-minority communities
  - Conduct analysis to identify key drivers of disparities
### Priorities for opioid settlement funding

<table>
<thead>
<tr>
<th>Priority</th>
<th>% ranked #1 priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery support services, including peer support and wrap-around services for individuals with Substance Use Disorder (SUD) and co-occurring mental health diagnoses</td>
<td>36%</td>
</tr>
<tr>
<td>Prevention programming</td>
<td>19%</td>
</tr>
<tr>
<td>Expanding access to Medications to treat Opioid Use Disorder (MOUD) and other opioid-related treatment</td>
<td>16%</td>
</tr>
<tr>
<td>Support for pregnant &amp; post-partum women affected by substance use, and infants with Neonatal Abstinence Syndrome (NAS)</td>
<td>9%</td>
</tr>
<tr>
<td>Naloxone distribution and training</td>
<td>7%</td>
</tr>
<tr>
<td>Treatment for incarcerated population</td>
<td>6%</td>
</tr>
<tr>
<td>Syringe Service Programs (SSP)</td>
<td>4%</td>
</tr>
<tr>
<td>Research and evaluation of abatement strategies</td>
<td>3%</td>
</tr>
</tbody>
</table>
### Treatment and Recovery Support Services

<table>
<thead>
<tr>
<th>Service</th>
<th>% ranked #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residential/inpatient treatment programming</td>
<td>24%</td>
</tr>
<tr>
<td>Wrap-around service programs to address spectrum of social factors (transportation, housing, employment, etc.)</td>
<td>20%</td>
</tr>
<tr>
<td>Access to Medications to treat Opioid Use Disorder (MOUD), including methadone, buprenorphine, and naltrexone</td>
<td>19%</td>
</tr>
</tbody>
</table>

### Prevention Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>% ranked #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence-based prevention programs in k-12 schools</td>
<td>28%</td>
</tr>
<tr>
<td>Training for first-responders on programming to connect at-risk individuals with services and supports</td>
<td>27%</td>
</tr>
<tr>
<td>Medical provider education and outreach around opioid prescribing best practices</td>
<td>25%</td>
</tr>
</tbody>
</table>

### Harm Reduction Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>% ranked #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expand programming to divert/deflect individuals from criminal-legal system</td>
<td>40%</td>
</tr>
<tr>
<td>Naloxone distribution and training</td>
<td>24%</td>
</tr>
<tr>
<td>Expanding capacity in existing Syringe Service Programs (SSPs) to provide more wrap-around services and linkages to treatment resources</td>
<td>22%</td>
</tr>
</tbody>
</table>

### Population/ Communities

<table>
<thead>
<tr>
<th>Community</th>
<th>% ranked #1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals with co-occurring mental health diagnoses and/or other Substance Use Disorders (SUD)</td>
<td>41%</td>
</tr>
<tr>
<td>Pregnant and post-partum women</td>
<td>13%</td>
</tr>
<tr>
<td>Rural communities</td>
<td>13%</td>
</tr>
</tbody>
</table>
NEXT STEPS AND QUESTIONS

- Webinars starting in April to inform best practices on services for opioid use disorder
  - Recovery – April 5
  - Harm reduction – April 19
  - Treatment – May 3
  - Prevention – May 17

- Future partnerships will be ongoing, and more information will be available later

- Questions?