City of Biddeford
City Council
January 02, 2018 6:00 PM Council Chambers

1. **Roll Call**
2. **Pledge of Allegiance**
3. **Adjustment(s) to Agenda**
4. **Game of Chance Beano/Bingo - Applications**
   - 4.a. Game of Chance & Beano/Bingo Applications: Rochambeau Club
     1-02-2018 Rochambeau Club-Game of Chance Apps.pdf
   - 4.b. Game of Chance Application: Heart of Biddeford (for WinterFest)
     1-02-2018 HOB Game of Chance App.pdf
5. **Consideration of Minutes:**
   - 5.a. December 12, 2017 Special Council Meeting Minutes
     12-12-2017 Special Council Meeting Minutes.docx
6. **Orders of the Day:**
   - 6.a. 2018.1) Amendment/Land Development Regulations/Art. III-Official Zoning Map/Rezone 8 Union Street and 283 Elm Street from B-2 to R-2 (Due to the urgency of the item, the 2nd Reading will take place immediately following the 1st reading)
     1-02-2018 Elm Street Rezoning-ORDER.docx
     1-02-2018 Elm Street Rezoning-MEMO.pdf
   - 6.b. 2018.2) Amendment/Land Development Regulations/Art. V-Establishment of Zones/Density and Setback Requirements in R-2 Zone
     1-02-2018 R2 Density-ORDER.docx
     1-02-2018 R2 Density-MEMO.pdf
   - 6.c. 2018.3) Amendment/Land Development Regulations/Add Water Supply System to Art. II-Definitions; Art. V-Establishment of Zones; and Art. VI-Performance Standards
     1-02-2018 Water Supply System(Essential Services)-ORDER.docx
     1-02-2018 Water Supply System(Essential Services)-MEMO.pdf
   - 6.d. 2018.4) Amendment/Land Development Regulations/Art. XIII-Amendments, Section 3-Contract and conditional zoning/Delete Contract Zones No. 2, No. 3 and No. 5
     1-02-2018 Delete Contract Zones 2, 3, 5 - ORDER.docx
     1-02-2018 Delete Contract Zones 2,3,5 - MEMO.pdf
   - 6.e. 2018.5) Amendment/Land Development Regulations/Art. V-Establishment of Zones/Correct Residential Cluster Subdivisions as Conditional Uses in B-2 Zone
     1-02-2018 Correct C in B2 Zone - ORDER.docx
     1-02-2018 Correct C in B2 Zone -MEMO.pdf
   - 6.f. 2018.6) Amendment/Ch. 42, Motor Vehicles & Traffic/Sec. 42-59-Snow emergency parking ban/Add Water Street Municipal Parking Lot
     1-02-2018 Snow emergency parking-add Water Street Lot.doc
   - 6.g. 2018.7) Authorization/Main Street Sidewalk Improvements Design Specifications/CDBG Expenditure
     1-02-2018 Main Street Sidewalk Improvement-ORDER.doc

1-02-2018 Main Street Sidewalk Improvement-Bid Specs.doc

6.h. 2018.8) Approval/Purchase and Sale Agreement to Exchange Property for 49 Center Street

1-02-2018 Center Street Property Exchange-Dan Adams-ORDER.doc
1-02-2018 Center Street Property Exchange-backup docs.pdf
1-02-2018 Center Street Property Exchange-MAP.pdf

6.i. 2018.9) Resolution/Authorization to Join Lawsuit Against Opiate Drug Companies

1-02-2018 Resolution-Opioid Lawsuit.doc
1-02-2018 Opioid Lawsuit-Contingent Fee Agreement.docx
1-02-2018 Opioid Lawsuit-Legal Report.pdf
1-02-2018 Opioid Lawsuit-Nassau County Complaint.pdf

7. Appointments:

7.a. Bob Mills...Cable T.V. Committee

1-02-2018 Appt-Mills-Cable TV Committee.docx
1-02-2018 Appt-Mills-Committee App.pdf

7.b. Toni Sipka...Cable T.V. Committee

1-02-2018 Appt-Sipka-Cable TV Committee.docx
1-02-2018 Appt-Sipka-Committee App.pdf

7.c. Julian Schlaver...Downtown Development Commission

1-02-2018 Appt-Schlaver-DDC.docx
1-02-2018 Appt-Schlaver-Committee App.pdf

7.d. Nathan Bean...Policy Committee

1-02-2018 Appt-Bean-Policy Committee.docx
1-02-2018 Appt-Bean-Committee App.pdf

7.e. Ad Hoc Community Center Committee

1-02-2018 Appts-Ad Hoc Community Center Comm.docx

8. City Manager Report

9. Public Addressing the Council..(5 minute limit per speaker; 30 minute total time limit)

10. Other Business

11. Council President Addressing the Council

12. Mayor Addressing the Council

13. Executive Session

13.a. 1 MRSA 405(6)(E)...Consultation with City Solicitor

14. Adjourn

FOR OFFICE USE ONLY

Check #_____

Amount $ _____

Beano/Bingo Registration

MGCU - 5000

The application and fees must be received at least eight days before the Beano/Bingo may begin

Beano/Bingo: $5.00/Special Per Game Registration; $12/Week; $36/Month; $400/Year

Make check payable to *Treasurer, State of Maine*

Return the completed and signed application to:
Department of Public Safety
Gambling Control Unit
Central Maine Commerce Center
87 State House Station
45 Commerce Drive, Suite 3
Augusta, Maine 04333-0087
(207) 626-3900 – Office
(207) 287-4356 – Fax

1. Organization Name: Rochambeau Club

Organization Number: 1256 Federal Tax ID # (EIN): 01-0226525

Business Address: 329 SouthSt

Biddeford, ME 04005

Mailing Address: Same Phone: 207 283-833

2. Current Officers:

Pres George Wonthley 20 Edgehill Dr Biddeford, ME 04005 207 602-6047 3/31/18
NAME & TITLE ADDRESS CITY/ZIP PHONE DATE TERM EXPIRES

Director Dave LaPierre 4 Burtheigh Ave Biddeford, ME 04005 207 282-3066 3/31/18
NAME & TITLE ADDRESS CITY/ZIP PHONE DATE TERM EXPIRES

Director Roger Roberts 1 Parkview ct Biddeford, ME 04005 207 710-2322 3/31/18
NAME & TITLE ADDRESS CITY/ZIP PHONE DATE TERM EXPIRES

Director Alvie Cote 91 Western Ave Biddeford, ME 04005 207 282-6829 3/31/18
NAME & TITLE ADDRESS CITY/ZIP PHONE DATE TERM EXPIRES

3. Location where Beano/Bingo is to be conducted:

Rochambeau club 329 south st Biddeford, ME 04005
BUILDING ADDRESS CITY/ZIP

4. Person responsible for operation of Beano/Bingo:

George Wonthley 207 590-1228 – 207 602-6047
NAME DAYTIME PHONE & EVENING PHONE

Name & Address where registration will be sent: Rochambeau Club 329 SouthSt Biddeford ME 04005

E-Mail Address:

5. Circle the days of the week you expect to operate: Mon Tue Wed Thu (Fri) Sat Sun

6. What time do the doors open? 4 pm What time does the game start? 6:15 p.m.

7. Dates – Please specify weeks (Monday through Sunday) or full months.

8. Does the organization own all the equipment used in operating this amusement? Yes ☑ No ☐

If "NO", please explain the circumstances under which the equipment was acquired:

9. Has any current officer of this organization or association ever been convicted of or have any charges currently pending for violating the gambling or lottery laws of the United States or the State of Maine? Yes ☐ No ☑

If "YES" give the person's name, address, and date and place of conviction or date and location of pending charge:

10. If the applicant is a Fair Association, attach a list of the names and home addresses of the persons operating or assisting in the registered activity. **Please write your organization name and number on the list.**

11. The following consent must be completed by the municipal officers of the city or town where the Beano/Bingo will take place unless a separate "Blanket Letter of Approval" is filed with the Gambling Control Unit.

☐ Check here if you have previously filed a "Blanket Letter of Approval" with us, which is still valid

☐ Check here if you have attached a "Blanket Letter of Approval".

Municipal Consent to Register

The undersigned being municipal officers of the City/Town of _____ hereby certify that we consent to the application for registration by _____ to operate Beano/Bingo in accordance with the provisions of 17 M.R.S.A. Chapter 13-A and in accordance with

the Rules and Regulations promulgated by the State of Maine, Department of Public Safety, Gambling Control Unit governing the operating of Beano/Bingo.

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

This approval is valid until: _____
(Date)

12. The applicant agrees to obey Federal, State of Maine laws, rules and regulations governing Beano promulgated by the Department of Public Safety, Gambling Control Unit. The applicant warrants the truth of the foregoing statements on penalty of perjury. Age 18 or older: Yes☐ No☐

Signed: George Worthley ID #: _____

Print Name: George Worthley Title: President

Date: _____

FOR OFFICE USE ONLY
Check #_____
Amount $ _____

Games of Chance License Application

MGCU - 5300

The application and fees must be received at least eight days before the Game of Chance may begin

Cards: $60/Calendar Month or $700/Calendar Year

Video Poker: $15/Week or $60/Month

Cribbage: $30 per Calendar Year or Portion Thereof

Super Cribbage Tournament Game: $75.00/Per Tournament

Tournament Game (up to 100 players): $75.00/Per Tournament; $200.00/Month (Two Tournaments per Month); $1,500/Year (Two Tournaments per Month)

Make check payable to *Treasurer, State of Maine*

Return the completed and signed application to:
Department of Public Safety
Gambling Control Unit
Central Maine Commerce Center
87 State House Station
45 Commerce Drive, Suite 3
Augusta, Maine 04333-0087
(207) 626-3900 – Office
(207) 287-4356 – Fax

1. For what game(s) are you licensing (please indicate number adjacent name):

Cards ✓ Video Poker ___ Cribbage ___ Super Cribbage Tournament ___ Tournament ___

Other ___ (If You Checked Other Indicate Name of Game and Attach the Rules for that Game)

Poker

2. Organization Name: Rochambeau Club

Organization Number: 1256 Federal Tax ID # (EIN): 01-0722525

Business Address: 329 South St

Biddeford, ME 04005

Mailing Address: Same Phone: 207 283-3833

3. Current Officers:

	NAME & TITLE	ADDRESS	CITY/ZIP	PHONE	DATE TERM EXPIRES
President	George Winthrop	20 Winthrop	Biddeford, ME 04005	207 602-6047	3/31/18
Director	Dave Lapierre	4 Birchgrove Ave	Biddeford, ME 04005	207 282-3069	3/31/18
Director	Roger Roberts	1 Parkview Ct	Biddeford, ME 04005	207 210-7322	3/31/18
Director	Alicia Cote	91 Western Ave	Biddeford, ME 04005	207 282-6829	3/31/18

4. Location where Game of Chance is to be conducted:

BUILDING	ADDRESS	CITY/ZIP
329 South St	Biddeford, ME	04005

5. Person responsible for operation of Game of Chance:

NAME	DAYTIME PHONE & EVENING PHONE
George Winthrop	207 540-1228 207 602-6047

Name & Address where license will be sent: Rochambeau Club 329 South St Biddeford, ME 04005

E-Mail Address: _____

6. Circle the days of the week you expect to operate: (Mon) Tue (Wed) (Thu) (Fri) (Sat) (Sun)

7. What time do the doors open? 4 pm What time does the game start? 7:00 pm

8. Dates – Please specify weeks (Monday through Sunday) or full months.

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

9. Does the organization own all the equipment used in operating this amusement? Yes☑ No☐

If "NO", please explain the circumstances under which the equipment was acquired:

_____

10. Has any current officer of this organization or association ever been convicted of or have any charges currently pending for violating the gambling or lottery laws of the United States or the State of Maine?
Yes☐ No☑

If "YES" give the person's name, address, and date and place of conviction or date and location of pending charge:

_____

11. If the applicant is a Fair Association, attach a list of the names and home addresses of the persons operating or assisting in the licensed activity. **Please write your organization name and number on the list.**

12. **Tournament Game Only**: Specify the name(s) of the charitable organization(s) that the proceeds of the tournament will benefit.

_____

_____

13. The following consent must be completed by the municipal officers of the city or town where the Game of Chance will take place unless a separate "Blanket Letter of Approval" is filed with the Gambling Control Unit.

☐ Check here if you have previously filed a "Blanket Letter of Approval" with us, which is still valid

☐ Check here if you have attached a "Blanket Letter of Approval".

Municipal Consent to License

The undersigned being municipal officers of the City/Town of _____ hereby certify that we consent to the application for license by _____ to operate Games of Chance in accordance with the provisions of 17 M.R.S.A. Chapter 62 and in accordance with the Rules and Regulations promulgated by the State of Maine, Department of Public Safety, Gambling Control Unit governing the operation of Games of Chance.

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

This approval is valid until: _____
(Date)

14. The applicant agrees to obey Federal, State of Maine laws, rules and regulations governing Games of Chance promulgated by the Department of Public Safety, Gambling Control Unit. The applicant warrants the truth of the foregoing statements on penalty of perjury. Age 18 or older: Yes☐ No☐

Signed: George Wortley

Print Name: George Wortley Title: President

Date: _____

FOR OFFICE USE ONLY
Check #_____
Amount $ _____

Games of Chance Registration

MGCU - 5400

The application and fees must be received at least eight days before the Game of Chance may begin

Games of Chance (Includes Raffles): $15/Week or $60/Calendar Month or $700/Calendar Year

Make check payable to *Treasurer, State of Maine*

Return the completed and signed application to:
Department of Public Safety
Gambling Control Unit
Central Maine Commerce Center
87 State House Station
45 Commerce Drive, Suite 3
Augusta, Maine 04333-0087
(207) 626-3900 – Office
(207) 287-4356 – Fax

1. For what game(s) are you registering (please indicate number adjacent name):

   Sealed Ticket ✓ Dice ___ Wheel ___ Pot of Gold (Includes Daily/Weekly Pool) ___ Raffle ___

   Other ___ (If You Checked Other Indicate Name of Game and Attach the Rules for that Game)

   Sealed tickets

2. Organization Name: Rochambeau Club

   Organization Number: 1256 Federal Tax ID # (EIN): 01-0226525

   Business Address: 329 South St

   Biddeford, ME 04005

   Mailing Address: Same Phone: 207 283-3833

3. Current Officers:

NAME & TITLE	ADDRESS	CITY/ZIP	PHONE	DATE TERM EXPIRES
Pres George Wonthley	20 Evan Thru Dr	Biddeford, ME 04005	207 602-6047	3/31/18
Director Dave Lapierre	4 Bucktheir Lane	Biddeford, ME 04005	207 282-3089	3/31/18
Director Roger Roberts	1 Park View Ct	Biddeford, ME 04005	207 710-2378	3/31/18
Director Aline Cote	91 Western Ave	Biddeford, ME 04005	207 282-6829	3/31/18

4. Location where Game of Chance is to be conducted:

BUILDING	ADDRESS	CITY/ZIP
Rochambeau Club	329 South St	Biddeford, ME 04005

5. Person responsible for operation of Game of Chance:

NAME	DAYTIME PHONE & EVENING PHONE
George Wonthley	207 590-7228 207 602-6047

   Name & Address where registration will be sent: Rochambeau Club 329 South St Biddeford, ME 04005

   E-Mail Address: ___

6. Circle the days of the week you expect to operate: (Mon) (Tue) (Wed) (Thu) (Fri) (Sat) (Sun)

7. What time do the doors open? 4 pm What time does the game start? _____

8. Dates – Please specify weeks (Monday through Sunday) or full months.

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

9. Does the organization own all the equipment used in operating this amusement? Yes☑ No☐

If "NO", please explain the circumstances under which the equipment was acquired:

_____

10. Has any current officer of this organization or association ever been convicted of or have any charges currently pending for violating the gambling or lottery laws of the United States or the State of Maine? Yes☐ No☑

If "YES" give the person's name, address, and date and place of conviction or date and location of pending charge:

_____

11. If the applicant is a Fair Association, attach a list of the names and home addresses of the persons operating or assisting in the licensed activity. **Please write your organization name and number on the list.**

12. **Raffles Only**: Specify the charitable purpose that the proceeds of the Raffle will benefit.

_____

13. The applicant agrees to obey Federal, State of Maine laws, rules and regulations governing Games of Chance promulgated by the Department of Public Safety, Gambling Control Unit. The applicant warrants the truth of the foregoing statements on penalty of perjury. Age 18 or older: Yes☑ No☐

Signed: George Wentley ID #: _____

Print Name: George Wentley Title: President

Date: _____

FOR OFFICE USE ONLY
Check #_____
Amount $ _____

Games of Chance License Application

MGCU - 5300

The application and fees must be received at least eight days before the Game of Chance may begin

Cards: $60/Calendar Month or $700/Calendar Year

Video Poker: $15/Week or $60/Month

Cribbage: $30 per Calendar Year or Portion Thereof

Super Cribbage Tournament Game: $75.00/Per Tournament

Tournament Game (up to 100 players): $75.00/Per Tournament; $200.00/Month (Two Tournaments per Month); $1,500/Year (Two Tournaments per Month)

Make check payable to *Treasurer, State of Maine*

Return the completed and signed application to:
Department of Public Safety
Gambling Control Unit
Central Maine Commerce Center
87 State House Station
45 Commerce Drive, Suite 3
Augusta, Maine 04333-0087
(207) 626-3900 – Office
(207) 287-4356 – Fax

1. For what game(s) are you licensing (please indicate number adjacent name):

   Cards ___ Video Poker ___ Cribbage X Super Cribbage Tournament ___ Tournament ___

   Other ___ (If You Checked Other Indicate Name of Game and Attach the Rules for that Game)

2. Organization Name: Heart of Biddeford

   Organization Number: 31290 Federal Tax ID # (EIN): 34 - 2003673

   Business Address: 205 Main Street, Suite 103 Biddeford, ME 04005

   Mailing Address: 205 Main Street, Suite 103 Biddeford, ME 04005 Phone: 207-284-8520

3. Current Officers:

NAME & TITLE	ADDRESS	CITY/ZIP	PHONE	DATE TERM EXPIRES
Delilah Poupore, Executive Director	205 Main Street, Suite 103 Biddeford, ME 04005			
Amy Grohman, President	9 Lisa Lane, Biddeford, ME 04005			
David Flood, Secretary	36 May Street, Biddeford, ME 04005			

4. Location where Game of Chance is to be conducted:

BUILDING	ADDRESS	CITY/ZIP
Pepperell Center, 40 Main Street, Biddeford, ME 04005		

5. Person responsible for operation of Game of Chance:

NAME	DAYTIME PHONE & EVENING PHONE
Delilah Poupoure	207-284-8520

Name & Address where license will be sent: Heart of Biddeford, 205 Main Street, Suite 103, Biddeford, ME 04005

E-Mail Address: office@heartofbiddeford.org director@heartofbiddeford.org

6. Circle the days of the week you expect to operate: Mon Tue Wed Thu Fri Sat (Sun)

7. What time do the doors open? 5:00 pm What time does the game start? 6:00pm

8. Dates – Please specify weeks (Monday through Sunday) or full months.

Sunday, February 4, 2018

9. Does the organization own all the equipment used in operating this amusement? Yes☒ No☐

If "NO", please explain the circumstances under which the equipment was acquired:

10. Has any current officer of this organization or association ever been convicted of or have any charges currently pending for violating the gambling or lottery laws of the United States or the State of Maine?
Yes☐ No☒

If "YES" give the person's name, address, and date and place of conviction or date and location of pending charge:

11. If the applicant is a Fair Association, attach a list of the names and home addresses of the persons operating or assisting in the licensed activity. **Please write your organization name and number on the list.**

12. **Tournament Game Only**: Specify the name(s) of the charitable organization(s) that the proceeds of the tournament will benefit.

Heart of Biddeford and Pepperell Mills LLC

13. The following consent must be completed by the municipal officers of the city or town where the Game of Chance will take place unless a separate "Blanket Letter of Approval" is filed with the Gambling Control Unit.

☐ Check here if you have previously filed a "Blanket Letter of Approval" with us, which is still valid

☒ Check here if you have attached a "Blanket Letter of Approval".

Municipal Consent to License

The undersigned being municipal officers of the City/Town of Biddeford hereby certify that we consent to the application for license by Heart of Biddeford to operate Games of Chance in accordance with the provisions of 17 M.R.S.A. Chapter 62 and in accordance with the Rules and Regulations promulgated by the State of Maine, Department of Public Safety, Gambling Control Unit governing the operation of Games of Chance.

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

Name: _____

Date: _____ Title: _____

This approval is valid until: _____
(Date)

14. The applicant agrees to obey Federal, State of Maine laws, rules and regulations governing Games of Chance promulgated by the Department of Public Safety, Gambling Control Unit. The applicant warrants the truth of the foregoing statements on penalty of perjury. Age 18 or older: Yes☐ No☐

Signed: _____

Print Name: _____ Title: _____

Date: _____

STATE OF MAINE
Department of Public Safety
Gambling Control Unit

87 State House Station
Augusta, Maine
04333-0087

PAUL R. LEPAGE
Governor

JOHN E. MORRIS
Commissioner

MILTON CHAMPION
Executive Director

TO: All Non-Profit Organizations

If your organization has never been established with us, please send the following documents along with your application:

- Charter papers, by-laws, etc. ✓
- Beneficiary statement, stating what will happen to the income in the event the organization should disband or dissolve. ✓ in by laws
- Membership list to include names, addresses, telephone numbers and original date of membership for officers and members conducting games. ✓
- A special financial account shall be opened to handle all deposits and disbursements relating to the operation (except Beano/Bingo running less than 10 occasions). ✓
- Copies of minutes of meetings to establish your organization has been in existence for at least two years. To show this, please send us minutes of your last meeting, and the minutes from the same month last year, and the year before. ✓
- Copy of the organization's determination letter that is issued by the IRS that shows tax exempt status.
- Copy of the IRS form 990 (Return of Organization Exempt from Income Tax) for previous two years. ✓
- Copy of the Articles of Incorporation and the current Annual Report issued by the Bureau of Corporations, Elections and Commissions Division of the Maine Secretary of State's Office.

If your organization needs further information please contact the Gambling Control Unit.

SPECIAL COUNCIL MEETING
DECEMBER 12, 2017

Mayor Casavant called the meeting to order at 6:00 p.m.

Roll Call: Michael Swanton, John McCurry, Jr., Stephen St. Cyr, Victoria Foley, Norman Belanger, Michael Ready, Marc Lessard
Laura Seaver arrived at 6:49 p.m.

Robert Quattrone, Jr. was excused.

The Council, and all who were present, recited the Pledge of Allegiance.

Adjustment to the Agenda:

- **Add Order 2017.140) Establishment of Summer Staffing Reserve Fund**

2017.140 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017
BE IT ORDERED, that the City Council of the City of Biddeford does hereby authorize the establishment of a Summer Staffing Reserve Fund funding it with $50,000 from unassigned fund balance.

Motion by Councilor McCurry, seconded by Councilor Lessard to grant the order.
Vote: Unanimous.

Game of Chance Application: **Fraternal Order of Eagles, #804**
Motion by Councilor McCurry, seconded by Councilor Lessard to recommend the issuance of the Game of Chance licenses to Fraternal Order of Eagles, #804.
Vote: Unanimous.

Public Heating: **Liquor License Application: Brown and Brown Hospitality, LLC dba Elda**
The Chair opened the public hearing at 6:07 p.m.
There were no public comments.
The public hearing was closed at 6:07 p.m.

Consideration of Liquor License Application: **Brown and Brown Hospitality, LLC dba Elda**
Motion by Councilor McCurry, seconded by Councilor Lessard to recommend the issuance of a liquor license to Brown and Brown Hospitality, LLC dba Elda.
Vote: Unanimous.

Presentation: **Parking Garage Design Proposals**
Members from Desman Design Management presented parking garage options for three possible sites within the City. The sites include: (1) Washington and Federal Street Lot; (2) Former Maine Energy Recovery Lot; and (3) Pepperell Plaza. It was noted that the City owns the two lots; however, does not own Pepperell Plaza.

Parking garage designs were shown for each proposed location, along with information on how many parking spaces would be incorporated in each design and the approximate costs for each design.

Presentation: **Winter Parking Update**
City Manager, James Bennett discussed the way snow event parking bans and snow removal parking bans will be handled this winter season. One of the biggest changes is that parking bans will now be posted to begin at a later time in some areas of the downtown. City Staff has also been working with the tow companies to ensure that they are willing and able to starting towing at a later hour.

Councilor McCurry suggested that the Council hold a workshop on this issue. Councilor Foley stressed that messaging to the public needs to be clear and consistent; and that the messaging needs to get out to all business owners and citizens alike.

Consideration of Minutes: **November 21, 2017**
Motion by Councilor Ready, seconded by Councilor Swanton to accept the minutes as printed.
Vote: Unanimous.

Orders of the Day:

2017.129 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED that the City Council of the City of Biddeford nominate and elect a Council President.

Motion by Councilor Ready to nominate Councilor John McCurry, Jr. as Council President, seconded by Councilor Swanton.
Vote: Unanimous.

2017.130 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED, that the City Council of the City of Biddeford does hereby adopt Roberts Rules of Order, in conjunction with the Code of Ordinances, Appendix A, Rules of the Council.

Motion by Councilor Lessard, seconded by Councilor McCurry to grant the order.

Motion by Councilor Belanger to amend Appendix A-Rules of the Council, Sec. A-1. Rule 1(j) – to change from three minutes per speaker to <u>five minutes per speaker.</u>
Vote on amendment: 7/1; Councilor Lessard opposed.
Councilors Swanton, McCurry, St. Cyr, Foley, Belanger, Ready and Seaver in favor.
Motion carries.

Vote on order, as amended: 7/1; Councilor Lessard opposed.
Councilors Swanton, McCurry, St. Cyr, Foley, Belanger, Ready and Seaver in favor.
Motion carries.

2017.131 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED, that Mayor Alan Casavant's appointment of **<u>STEPHEN ST. CYR</u>** to the Finance Committee be confirmed.

Motion by Councilor Belanger, seconded by Councilor Lessard to confirm the appointment.
Vote: Unanimous.

2017.132 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED, that the Council President's appointment to the Finance Committee be confirmed.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the Council President's appointment of **<u>Michael Ready</u>** to the Finance Committee.
Vote: Unanimous.

2017.133 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED, that Mayor Casavant's appointment of Keith R. Jacques and the firm of Woodman Edmands Smith Danylik, Austin & Jacques, P.A., as City Solicitor, in accordance with the Charter of the City of Biddeford be confirmed.

Motion by Councilor Ready, seconded by Councilor Lessard to confirm the appointment of Keith Jacques, Esq. as City Solicitor.
Vote: Unanimous.

2017.134 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017

BE IT ORDERED, that I, Alan Casavant, Mayor of the City of Biddeford, do hereby appoint the following Councilors to the CAPITAL PROJECTS/OPERATIONS COMMITTEE:

Robert Quattrone Jr., CHAIR
Victoria Foley
Laura Seaver

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointments.
Vote: Unanimous.

2017.135 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017
BE IT ORDERED, that I, Alan Casavant, Mayor of the City of Biddeford, do hereby appoint the following Councilors to the PERSONNEL COMMITTEE:

John McCurry, Jr., CHAIR
Norman Belanger
Michael Ready
Stephen St. Cyr

Motion by Councilor Ready, seconded by Councilor Lessard to confirm the appointments.
Vote: Unanimous.

2017.136 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017
BE IT ORDERED, that I, Alan Casavant, Mayor of the City of Biddeford, do hereby appoint the following Councilors to the POLICY COMMITTEE:

Laura Seaver, CHAIR
Norman Belanger
Marc Lessard

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointments.
Vote: Unanimous.

2017.137 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017
BE IT ORDERED, that I, Alan Casavant, Mayor of the City of Biddeford, do hereby appoint the following Councilors to the following committees and commissions:

Cable TV Committee: ***Michael Swanton***

Downtown Development Commission: ***Victoria Foley***

Saco Joint Committee: ***Michael Ready; Michael Swanton***

Solid Waste Management Commission: ***Marc Lessard; Michael Swanton***

Wastewater Management Commission: ***Robert Quattrone, Jr.***

York County Budget Committee: ***Marc Lessard***

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointments.
Vote: Unanimous.

2017.138 IN BOARD OF CITY COUNCIL..DECEMBER 12, 2017
BE IT ORDERED, that the City Council of the City of Biddeford does here approve the purchase of Wearable Video System (Body Cam) from WatchGuard Inc. of Allen Texas, for the Biddeford Police Department; with a total purchase price of $47,040. This purchase is funded through C.I.P.

Motion by Councilor McCurry, seconded by Councilor Lessard to grant the order.
Vote: 7/1; Councilor Swanton opposed.
Councilors McCurry, St. Cyr, Foley, Belanger, Ready, Seaver and Lessard in favor.
Motion carries.

2017.139 IN BOARD OF CITY COUNCIL…. DECEMBER 12, 2017
BE IT ORDERED, that the City Manager be authorized to accept EPA 319 grant funds on behalf of the City, in the amount of not to exceed $139,790 for the implementation of the identified work plan in the initial phase of the Thatcher brook Watershed Implementation Project, Phase 1. An additional $99,521 will be contributed to the total project cost from local match funds and in kind services. The total estimated project cost of $239,311 includes costs for consulting services (to include such services as permitting, preliminary and final design, grant procurement/administration, bidding services, construction administration, and resident engineering), advertising expenses, and other costs as may be necessary for the implementation of the work plan.elements to improve the water quality in the Thatcher Brook Watershed as identified in the approved Thatcher Brook Watershed Master Plan and in the approved grant.

NOTE: This project will be funded 58.4% (not to exceed $139,790) from an EPA grant and 41.6% (not to exceed $99,521) from local matching funds and in kind services. This implementation plan is required to address water quality issues in the Thatcher Brook Watershed. Local Match funding for this project was approved as CIP items in fiscal years 2017 and 2018.

BE IT FURTHER ORDERED, that the City Manager be authorized to contract with the York County Soil and Water Conservation District, the project sub-grantee, in the amount of not to exceed $49,790, to extend their previous services provided during the development and acceptance of the Thatcher Brook Watershed Master Plan, these services to include planning, permitting, preliminary and final design assistance, grant procurement/administration, bidding services, construction administration, and engineering for upcoming implementation work. This amount of the contract is included in the $239,311 estimated total project cost, which will be funded 58.4% from EPA funds and 41.6% from local match and in kind services. Local Match funding for this project was included as part of the CIP items in fiscal years 2017 and 2018.

BE IT FURTHER ORDERED, that the City Manager be authorized to sign contracts with the lowest qualified bidder (contractor) to provide any construction services for upcoming implementation of watershed improvement projects. The amount of these contracts are included in the $239,311 estimated total project cost, which will be funded 58.4% from the EPA grant and 41.6 % from local match and in kind services provided. This contract work amount was included in the total project budget and will be implemented in fiscal years 2018 and 2019.

BE IT FURTHER ORDERED, that the City Manager be authorized to accept additional EPA 319 grant funds on behalf of the City, for use in implementing the work in Phase 1 of this project should such additional funds become available.

Motion by Councilor McCurry, seconded by Councilor Lessard to grant the order.
Vote: Unanimous.

Appointments:

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Frederick Oliver
316 Granite Street
Ward 3

to the *Airport Commission,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment.
Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Dean Tourigny
12 Thatcher Brook Lane
Ward 6

to the *Airport Commission,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment.
Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Anne Daly
170 Hills Beach Road
Ward 1

to the *Biddeford Housing Authority,* for a term to expire in December 2022.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Lucien Belanger
7 Debbie Avenue
Ward 3

to the *Cable T.V. Committee,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Daniel P. Boucher
72 Hill Street, Apt. 102
Ward 2

to the *Capital Projects Committee,* for a term to expire in December 2019.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby appoint:

Robert Provencher
38 Western Avenue
Ward 6

to the *Capital Projects Committee,* for a term to expire in December 2019.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Kenneth Buechs
10 Seal Lane
Ward 1

to the *Conservation Commission,* for a term to expire in December 2022.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Joyce Locke
56 Guinea Road
Ward 1

to the *Economic Improvement Commission,* for a term to expire in December 2024.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Larry Patoine
24 Appleridge Drive
Ward 6

to the *Planning Board* for a term to expire December 2020; as well as be appointed as the CHAIR of the *Planning Board* for 2018.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-designate:

Clement Fleurent
291 Granite Street
Ward 3

on the *Planning Board* from Associate Member to Full Voting Member, for a term to expire December 2018.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Renee O'Neil
48 Sevigny Avenue
Ward 2

to the *Policy Committee,* for a term to expire in December 2019.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Charlotte Jacques
1 Hillside Avenue
Ward 4

to the *Project Canopy Committee,* for a term to expire in December 2022.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Ron Ouellette
308 Pool Street
Ward 2

to the *Recreation Commission,* for a term to expire in December 2022.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

David Morissette
8 Rosewood Circle
Ward 3

to the *Shellfish Conservation Committee,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Roland Pelletier
10 Debbie Avenue
Ward 3

to the *Shellfish Conservation Committee,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

James Emerson
127 Old Pool Road
Ward 1

to the *Solid Waste Management Commission,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

IN BOARD OF CITY COUNCIL…DECEMBER 12, 2017

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Brian Fleurant
77 Prospect Street
Ward 4

to the *Wastewater Management Commission,* for a term to expire in December 2020.

Motion by Councilor McCurry, seconded by Councilor Lessard to confirm the appointment. Vote: Unanimous.

City Manager Report:
City Manager, James Bennett, on behalf of all City Staff, wished everyone Happy Holidays and a Happy and Prosperous New Year!

Public Addressing the Council…(3 minute limit per speaker; 30 minute total time limit)
There were no public comments.

Other Business:
Councilor Lessard: wished everyone a Merry Christmas and Happy Holidays; and safety to all City Staff who will be working during the holidays.

Councilor Swanton: at a previous meeting, he had asked for a copy of the Lincoln Street Property Feasibility Study and still has not received it. The City Manager stated that he will get that out to all the Councilors.

Councilor Swanton corrected a recent article in the Journal Tribune by stating that he was not wearing a tuxedo to the Inauguration.

Councilor Belanger: would like a discussion on the JDA and whether there's been a default.

Councilor Ready: asked where the City is with the *Delivery of Unsolicited Materials* ordinance enforcement. City Attorney, Keith Jacques responded that the newspapers' lawyers have been contacted twice and there has been to response as of yet.

Council President Addressing the Council: Councilor McCurry thanked his fellow Councilors for their vote and support in keeping him as the Council President for another term. He looks forward to working with everyone again.
Councilor McCurry wished everyone a very Merry Christmas.

Mayor Addressing the Council: Mayor Casavant thanked all who participated in and shared in making the recent Inauguration a success; and he especially thanked City Clerk, Carmen Morris for coordinating everything.
Mayor Casavant wished all a Merry Christmas and a Happy New Year.

Motion by Councilor McCurry, seconded by Councilor Lessard to adjourn.
Vote: Unanimous. Time: 7:22 p.m.

Attest by:_____
Carmen J. Morris, City Clerk

2018.1 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

BE IT ORDAINED by the City Council of Biddeford, Maine to amend the Code of Ordinances of the City of Biddeford as follows:

Part III (Land Development Regulations), Article III (Official Zoning Map), is amended to rezone the following parcels from B-2 to R-2:

8 Union Street (Tax Map 34, Lot 135) and 283 Elm Street (Tax Map 34, Lot 136).

Note: Following a duly noticed Public Hearing the Planning Board recommended that this approval be adopted by a 4-0 vote.

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, AICP
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

MEMORANDUM

To: Mayor Casavant
Council President McCurry & Members of City Council
J. Bennett, City Manager

From: Greg Tansley, AICP, City Planner

Date: December 14, 2017

Re: Proposed Amendments to Rezone Certain Properties on Elm Street from B-2 to R-2

The origin of this proposed amendment is from St. Joseph's Convent/St. Andres Home. The nuns are currently housed at 290 Elm Street across the street from 283 Elm Street. 290 Elm Street is currently for sale and has an option on it to purchase it by a private individual. The intent is for the nuns to relocate residency to 283 Elm Street which cannot happen so long as it is zoned B-2.

In reviewing the area it was noted that 8 Union and 287 Elm Street are both multi-family residential and are non-conforming since they are in a B-2 Zone. The original thought from Staff was to re-zone all three (283 Elm St., 287 Elm St., and 8 Union St.) as R-2 which is a residential zone immediately adjacent to the parcels. The owners of 287 Elm Street, however, came forward and requested that their parcel not be included in the rezoning, which Staff have no issues with. The Planning Board agreed not to include it in their recommendation.

As such, only 8 Union Street and 283 Elm Street have been recommended by the Planning Board for rezoning.

The Planning Board held the Public Hearing on December 6, 2017 and unanimously recommended the Ordinance Amendments to pass at the City Council.

Please let me know if you have any questions about this item before the January 2, 2018 City Council meeting.

Cc: File

City of Biddeford

2018.2 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

BE IT ORDAINED by the City Council of Biddeford, Maine to amend the Code of Ordinances of the City of Biddeford as follows:

Part III (Land Development Regulations), Article V (Establishment of Zones), Table B (Dimensional Requirements):

Zoning District	Minimum Lot Size, Square Feet Per Unit A				Frontage			Minimum Setback, Feet**				Maximum Heights+	
	Water and Sewer	Water, No Sewer	Sewer, No Water	Neither Water Nor Sewer	Water and Sewer	Water or Sewer	Neither Water Nor Sewer	From Major R.O.W.	From Other R.O.W	Side	Rear	Stories	Feet
R-2~~, single-family~~	~~10,000~~ 4,500	N/A	N/A	N/A	~~75~~ 45	N/A	N/A	~~40~~ 25	~~25~~ 15	~~10~~ 5	~~10~~5	3	35
~~R-2, duplex~~	~~7,500~~	~~N/A~~	~~N/A~~	~~N/A~~	~~100~~	~~N/A~~	~~N/A~~	~~40~~	~~25~~	~~10~~	~~10~~	~~3~~	~~35~~
~~R-2, multifamily~~	~~5,000~~	~~N/A~~	~~N/A~~	~~N/A~~	~~100~~	~~N/A~~	~~N/A~~	~~40~~	~~25~~	~~10~~	~~10~~	~~3~~	~~35~~
~~R-2, all other~~	~~10,000~~	~~N/A~~	~~N/A~~	~~N/A~~	~~100~~	~~N/A~~	~~N/A~~	~~40~~	~~25~~	~~10~~	~~10~~	~~3~~	~~35~~

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, AICP
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

MEMORANDUM

To: Mayor Casavant
Council President McCurry & Members of City Council
J. Bennett, City Manager

From: Greg Tansley, AICP, City Planner

Date: December 14, 2017

Re: Proposed Amendments related to reducing density and setback requirements in the R-2 Zone

---

On November 9, 2017 the City Council requested that the Planning Board hold a Public Hearing an make a recommendation back to the City Council about the proposed amendment to reduce the lot size and setback requirements in the R-2 Zone. The only concern raised by one Board Member (Mr. Fleurent) was related to the side setbacks being only 5' which I believe was the reason for his dissenting vote.

However, 5' setbacks ensures 10' separation of buildings which seems reasonable in a built-up urban area such as the R-2. Further, if a lot were 45' x 100' (4,500 SF) a 5' setback provides for a 35' building window. If the side setbacks were increased to 10', however, the building window becomes only 25' which is not much to work with on a narrow lot (i.e., creates an unreasonable building window).

The Planning Board held the Public Hearing on December 6, 2017 and by a vote of 3-1 recommended the Ordinance Amendments to pass at the City Council.

Please let me know if you have any questions about this item before the January 2, 2018 City Council meeting.

Cc: File

2018.3 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

BE IT ORDAINED by the City Council of Biddeford, Maine to amend the Code of Ordinances of the City of Biddeford as follows:

Part III (Land Development Regulations), Article II (Definitions) as follows:

ESSENTIAL SERVICES - Gas, electrical or communication facilities; steam, fuel, electric power or water transmission or distribution lines, towers and related equipment; telephone cables or lines, poles and related equipment; gas, oil, water, slurry or other similar pipelines; municipal sewage lines, collection or supply systems; and associated storage tanks. Such systems may include towers, poles, wires, mains, drains, pipes, conduits, cables, fire alarms and police call boxes, traffic signals, hydrants and similar accessories~~,~~. In a Shoreland Zone Essential Services~~but~~ shall not include service drops, buildings which are necessary for the furnishing of essential services, telecommunications facilities~~,~~ or small wind energy systems. Essential services shall be exempt from the dimensional requirements in Article V, Section 6A and Article V, Section 7.

WATER SUPPLY SYSTEM - The system for the collection, treatment, storage, and distribution of potable water from the source of supply to the consumer, including those buildings necessary to support the water supply system.

Part III (Land Development Regulations), Article V (Establishment of Zones), Table A (Table of Land Uses):

	Article VI Section[1]	W-3
Educational, institutional public uses		
Essential Services	27	C

Add "Water Supply System" as a Conditional Use (C) in all zones.

Part III (Land Development Regulations), Article VI (Performance Standards), Section 27 (Essential Services):

Section 27. Essential services and Water Supply Systems. [Ord. No. 2008.79, 10-21-2008]

A. Where feasible, the installation of essential services shall be limited to existing public ways and existing service corridors.

B. ~~Essential services shall require a conditional use permit from the Planning Board except that municipal essential services and essential services that are otherwise subject to review under subdivision review, site plan review, or shoreland zoning shall not require a conditional use permit.~~

C. (Reserved)[9]

D. Essential services and water supply systems structures and facilities shall be sited and developed in accordance with the provisions stated in this ordinance.

E. All conditional use permit applications for essential services and water supply systems shall include an assessment of potential environmental and health impacts to abutting properties as a result from noise, vibrations, fumes, odor, dust, glare, hours of operation, or other causes as applicable, unless a waiver is requested by the applicant and granted by the Planning Board.

Note: Following a duly noticed Public Hearing the Planning Board recommended that this approval be adopted by a 4-0 vote.

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, AICP
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

MEMORANDUM

To: Mayor Casavant
Council President McCurry & Members of City Council
J. Bennett, City Manager

From: Greg Tansley, AICP, City Planner

Date: December 14, 2017

Re: Proposed Amendments related to Water Supply Systems and Essential Services

---

This Ordinance Amendment came about following discussion with *Maine Water Company* regarding its plans to construct a new Water Treatment Facility off South Street in Biddeford. Based on a review of the definition of "Essential Services", a Water Treatment Facility does not fall under that definition. We cannot amend the definition since doing so would not be consistent with the definition permitted by the State in Shoreland Zoning.

As such, Staff recommend adding a new definition for "Water Supply System" and allowing it as a Conditional Use (C) in all zones subject to the Performance Standards currently in existence for Essential Services. We also recommend amending the Ordinance to correct and error related to allowing Essential Services as a Conditional Use in the W-3 Zone which appears to have been an omission.

The Planning Board held the Public Hearing on December 6, 2017 and unanimously recommended the Ordinance Amendments to pass at the City Council.

Please let me know if you have any questions about this item before the January 2, 2018 City Council meeting.

Cc: File

2018.4 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

BE IT ORDAINED by the City Council of Biddeford, Maine to amend the Code of Ordinances of the City of Biddeford as follows:

Part III (Land Development Regulations), Article XIII (Amendments), Section 3 (Contract and conditional zoning):

~~Contract Zone No. 2: Mike Eon Associates (Map 2, portion of Lot 42). (Not implemented)~~
~~Contract Zone No. 3: High School Associates (Map 34, Lot 228). (Not implemented)~~
~~Contract Zone No. 5: Coastal Savings Bank (Map 27, Lot 95-1). (Not implemented)~~

Note: Following a duly noticed Public Hearing the Planning Board recommended that this approval be adopted by a 4-0 vote.

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, AICP
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

MEMORANDUM

To: Mayor Casavant
Council President McCurry & Members of City Council
J. Bennett, City Manager

From: Greg Tansley, AICP, City Planner

Date: December 14, 2017

Re: Proposed Amendment to Delete Contract Zones 2, 3, and 5

Contract Zones 2, 3, and 5 were never implemented. This amendment simply cleans up the Ordinance to reflect that. The parcels on which contract Zones 3 (J Richard Martin Community Center) and 5 (McArthur Home for the Aged at 350 Elm Street) have since been put to other uses. Contract Zone 2 was put forward by Mike Eon Associates but never carried through with. Mike Eon spoke at the Public Hearing and has no issues with deleting its reference from the Ordinance.

The Planning Board held the Public Hearing on December 6, 2017 and unanimously recommended the Ordinance Amendments to pass at the City Council.

Please let me know if you have any questions about this item before the January 2, 2018 City Council meeting.

Cc: File

2018.5 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

BE IT ORDAINED by the City Council of Biddeford, Maine to amend the Code of Ordinances of the City of Biddeford as follows:

Part III (Land Development Regulations), Article V (Establishment of Zones), Table A (Table of Land Uses):

	Article VI Section[1]	B-2
Residential uses		
Cluster development*	18	~~C~~

Note: Following a duly noticed Public Hearing the Planning Board recommended that this approval be adopted by a 4-0 vote.

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, AICP
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

MEMORANDUM

To: Mayor Casavant
Council President McCurry & Members of City Council
J. Bennett, City Manager

From: Greg Tansley, AICP, City Planner

Date: December 14, 2017

Re: Proposed Amendment to Correct Residential Cluster Subdivisions as Conditional Uses in the B2 Zone

---

The proposed change corrects an apparent error in the Table of Land Uses that came about from a Zoning Amendment in 2000 related to the Rural-Farm Zone. This was an apparent error since by definition residential uses are not permitted in the B-2 Zones:

Land Development Regulations, Article V, Section 2: "B-2: These are highway-oriented commercial areas. Residential development is prohibited from this zone."

The Planning Board held the Public Hearing on December 6, 2017 and unanimously recommended the Ordinance Amendments to pass at the City Council.

Please let me know if you have any questions about this item before the January 2, 2018 City Council meeting.

Cc: File

City of Biddeford

2018.6 **IN BOARD OF CITY COUNCIL..JANUARY 2, 2018**

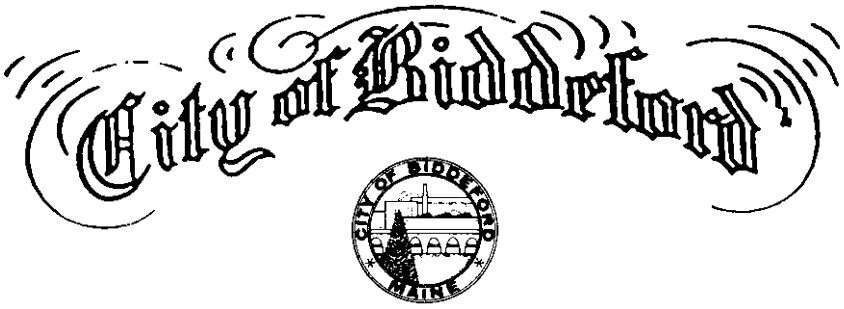
BE IT ORDAINED, by the City Council of the City of Biddeford that the Code of Ordinances, Chapter 42, Motor Vehicles and Traffic, Article III Parking, Stopping and Standing, **Section 42-59 Snow emergency parking ban** be amended by adding the following:

The following provisions shall apply during snow emergencies as declared by the director of public works:

(1) When the director of public works deems it necessary to allow for the safe and efficient removal of snow and ice from the public ways within the city, the director may declare that a snow emergency exists. The director of public works will announce the snow emergency by notifying the local radio and television media, and request that they make periodic announcements of the parking ban. The director will state in his notice, that during the hours of the emergency, parking of motor vehicles is prohibited on any way or municipal parking lot within the jurisdiction of the city, except that the municipal parking lots at the Community Center (Myrtle Street side only), Foss Street, Washington Street, Clifford Park, the Gas House and the Water Street parking lot are open for parking during the period of the emergency.

(2) A vehicle parked in violation of the declared snow emergency shall be towed at the owner's expense.

(3) Vehicles parked in the Foss Street and Washington Street, Clifford Park, Community Center, Gas house and Water Street municipal parking lots as authorized by this section must be removed prior to 7:00 a.m. on the day of the end of the snow emergency, and these municipal parking lots may not be used until they have been cleared of snow.



2018.7 IN BOARD OF CITY COUNCIL..JANUARY 2, 2018

BE IT ORDERED, that the City Council of the City of Biddeford does hereby authorize the expenditure of CDBG funds by the City Manager in the amount not to exceed $48,000 for the development of design specifications Main Street sidewalk improvements from Adams to Elm Street. The CDBG funds will be used for engineering and design specifications ($36,000), Surveying ($6,000), and for Printing, advertising, bidding services, etc. ($6,000). The Manager is authorized to seek RFQ for such services consistent with CDBG procurement services and reserves the right negotiate the final contract, in the best interests of the City and the CDBG program.

Request for Proposals
Survey, Design, Engineering, Construction Ready Plans and Bid Specifications Package for
Main Street Sidewalk Improvement Extension Project
Adams Street to Elm Street

The City of Biddeford will receive sealed proposals for survey, design, engineering, construction ready plans, and a bid specification package for the HUD – CDBG – Main Street Sidewalk Improvement Extension Project (2018) until **2:00 p.m.** prevailing local time **January 29th, 2018** at the Economic and Community Development Office, City Hall, 205 Main Street, Biddeford, Maine 04005. **Proposal documents (3 copies)** shall be in clearly marked sealed envelopes titled HUD – CDBG – Main Street Sidewalk Improvement Extension Project (2018). **All proposals will be opened in the Second Floor Conference Room in City Hall Council Chambers on January 29th, 2018 at 2:00 p.m.**

The Scope of Work includes the survey, design and engineering for sidewalk reconstruction from Adams Street to Elm Street (Both North and South sides) and includes such amenities as crosswalks, bumpouts, lighting (identical to lighting on Main Street between Water Street and Adams Street), and streetscaping (i.e. plantings, seating, etc.). The Scope of Work also includes the development of construction ready plans and a bid specification package.

A copy the RFP document for the work may be examined at the City of Biddeford's Engineering Office (3rd floor), 205 Main Street, Biddeford, Maine 04005 or a PDF file requested from John Malloy at the email below. Submit technical questions in writing to the attention of: John Malloy at 284-9118, or e-mail: Jonathan.Malloy@biddefordmaine.org and administrative and/or HUD regulation questions to Linda Waters at 284-9105 or, email: lwaters@biddefordmaine.org. no later than 5 days before the scheduled bid opening.

The City of Biddeford reserves the right to reject any or all proposals, to waive any technical or legal deficiencies, and to accept any Bid that it may deem to be in the best interests of the City of Biddeford, to negotiate the contract Price with any Bidder, and to omit any item or items deemed advisable for the interest of the City of Biddeford.

Proposals or amendments received after the deadline will not be considered. Faxed or E-mailed proposals will not be considered. Final award of the contract is anticipated to be on Tuesday, February 6th, 2018.

Federal Requirements

The Consultant must comply with all the Safety and Health Regulations (CFR29 part 1926 and all subsequent amendments) as promulgated by the US Department of Labor on June 24, 1974, the Department of Labor Regulations relating to Copeland Anti-Kickback Act (18 U.S. C. 874) as supplemented by 29 CFR part 3, Contract Work Hours and Safety Standards Act (40 U.S.C. 327-330) as supplemented by 29 CFR part 5, and Occupational Safety and Health Standards (OSHA) (29 CFR part 1910). The Consultant must comply with all applicable standards, orders, or requirements issued under section 306 of the Clean Air Act (42 U.S.C. 1857(h)), section 508 of the Clean Water Act (33 U.S.C. 1368), and Executive Order 11738. Consultants are urged to become familiar with the requirements of these regulations.

Nondiscrimination in Employment and Labor Standards

Bidders on this work will be required to comply with the President's Executive Order No. 11246 and amendments or supplements to that Order.

Proposal Format and Required Information

1. Summary
   Provide a brief summary of the Consultant's understanding of the project and relevant knowledge/experience. Provide information on all collaborators if more than one firm is involved.

2. Certification
   Each proposal must include a letter that the Consultant has visited and inspected the project site and is familiar with conditions at the site.

3. Work Plan
   Provide an outline of the approach proposed to accomplish the Scope of Services and the manner in which the consultant will work with City of Biddeford and the designated Project Manager in coordinating the project. Creative approaches to completing the project and any suggested additional approaches are encouraged. Inclusion of two public meetings to review the design and one presentation before City Council is required in the Work Plan. Suggestions must be clearly identified as optional approaches. In any event, a cost must be included for the Scope of Work defined in this Request for Proposals. A separate cost breakdown for any proposed additional items shall be provided apart from the Scope of Work outlined herein.

4. Qualifications
   Provide a description of the Consultant's qualifications, capabilities, and organizational structure. Identify the project team including qualifications, experience, and specific responsibilities of the project manager and staff that will be assigned to the project (include a resume for each person).

5. Relevant Work Experience and References
   Provide examples of projects similar in scope and scale completed by the Consultant, especially related to similar work for municipal entities (by the staff that would be assigned to this project if possible). Provide a brief description including completion date, type and scope of project, and contact person with telephone number for reference.

6. Work Schedule
   Provide a detailed schedule indicating how the project tasks will be organized to complete the work. The schedule must include a matrix of the project tasks and hours assigned broken down by personnel assigned to each task. (Work is expected to be completed 60 days after the contract signing)

7. Insurances
   Provide proof of Workman's Compensation insurance, liability insurance of at least $300,000 combined single limit and professional liability insurance. During the term of the contract, the Consultant agrees to maintain such insurance and provide the City with current proofs of insurance.

8. Indemnification
   Acknowledge that the selected Consultant shall agree to indemnify and hold the City harmless from claims, demands, suits, causes of action and judgments arising from the Consultants performance including claims of professional malpractice or negligence.

9. Cost Proposal
   The Consultant's proposed budget and "not to exceed" cost for completing the project must include a task breakdown of project cost by each staff/team member and hours assigned to each staff/team member.

Modification of Proposals

Modifications to proposals received prior to the submission deadline will be accepted, and must be submitted in a sealed envelope identifying the name and address of the consultant and clearly marked "MODIFICATION TO PROPOSAL – CITY OF BIDDEFORD MAIN STREET SIDEWALK IMPROVEMENT EXTENSION PROJECT", along with the date of modification and modification number.

Three (3) copies of modifications to the proposal shall be submitted. Modifications shall include insertion pages or replacement pages and a transmittal letter explaining the reason for the modification and a detail indexing the modifications. The City will not be responsible for misdirected or poorly labeled modifications.

Selection Process

Upon release of this RFP, the City will be responsible for the review of project proposals and the selection of a recommended qualified project design/engineering Consultant. All Proposals will be opened after the "Deadline for Submitting Proposals" and be available for public inspection. A register of all applications will be prepared.

Proposals will be evaluated based on technical merit and on the criteria listed below. Finalists may be interviewed as part of the evaluation process. After the evaluation and interviews are completed, the Consultant Selection Committee will rank the finalists and recommend to the Biddeford Finance Committee and City Council that a contract be awarded to the Consultant submitting the proposal most favorable to the Consultant Selection Committee and the City of Biddeford. Additional copies of proposals may be required from Consultants at this stage, to be provided at the sole cost of the Consultant.

Evaluation Criteria

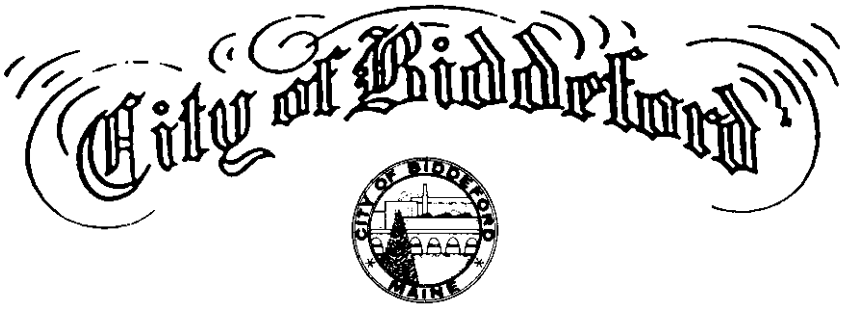
1. Comparative costs of the proposals will be considered, but will not be the only basis for selection.
2. Submission of a complete proposal with the Consultant's approach to the project, which contains all information, services, and requirements in this RFP in as brief a format as possible. Proposals shall be no more than 20 pages (single sided), not including the cover page and resources of the consulting team.
3. Thoroughness and comprehensiveness of services the Consultant proposes to provide.
4. Letter of site inspection and familiarization with the project.
5. Stated ability to execute a contract within 1 week of selection, and to perform and complete all work as indicated in the final Scope of Services.
6. Overall Consultant experience and past performance on similar projects.
7. Stated ability to appear for an interview, if requested.
8. Adequate assigned resources and staffing to do the work.
9. Concept and process creativity.

Miscellaneous

1. All proposals submitted in response to this RFP become the property of the City of Biddeford. The City of Biddeford has the right to disclose information contained in the proposals after an award has been made. All submitted reports, documents, and materials shall be considered public information and shall be the

property of the City of Biddeford. All products, both paper and digital, and borrowed materials shall be delivered to the Project Manager prior to final payment.

2. The City of Biddeford specifically reserves the right to reject or request modification of any and all proposals if it is determined by the Consultant Selection Committee, Finance Committee, or City Council to be in the best interests of the City. In rating the interviewed consultants, if interviews are held, the City shall consider the value of the services to be rendered, the scope of the proposal, past experience with the consultant, references contacted and the professionalism of the team.



2018.8 IN BOARD OF CITY COUNCIL..JANUARY 2, 2018

BE IT ORDERED, that the City Council of the City of Biddeford does hereby approve the City Manager to sign a purchase and sale agreement to exchange 57 Pike Street for 49 Center Street, release the current right of way, and reserve approximately seven fee to Dan Adams.

CITY OF BIDDEFORD, MAINE

COMMUNITY & ECONOMIC DEVELOPMENT DEPARTMENT

205 Main St.
P.O. Box 586
Biddeford, Maine 0400

TO: **James Bennett, City Manager**
Mayor Alan Casavant
City Councilors

FROM: **Linda Waters, Community Development Coordinator**

DATE: **December 26th, 2017**

ACTION: **Approval for the City Manager to sign a purchase and sale agreement to exchange 57 Pike Street for 49 Center Street, release the current right of way, and reserve approximately seven feet to Dan Adams.**

The City has been working with Dan Adams, the owner of 49 Center Street (the old driving school), to explore the possibility of a property exchange. This process has been implemented over the last 3 plus years. The reason for the idea of an exchange was brought about by the construction of Williams Court Park. For many years, properties (now gone) were accessed through a path next to Mr. Adam's property on Center Street. After the park was constructed it was brought to the City's attention that people were still accessing this pathway and crossing into Mr. Adam's property. After several meetings it was proposed by the then city administration that if a suitable property was found in City ownership that there could be the possibility of an exchange for 49 Center Street. The City would have a potential pathway into the park and numerous problems would be eliminated for Mr. Adams. It should be noted that at some point in the future an official entrance to the park on Center Street is a possibility. The packet included with this memo describes the process that Dan Adams and the City have taken to ensure the property has completed historic and environmental reviews, and code requirements since it is proposed that the building at 49 Center be demolished. The property at 49 Center is valued at $59,900 and the building on site is unoccupied. The property to be exchanged is a vacant city owned property at 57 Pike Street. The Pike Street property is valued at $33,300. This approval will also provide for release of the current right of way held by the City. Also, in the exchange is reservation of approximately seven feet to Mr. Adams (see survey map).

In addition, Mr. Adams will absorb all costs of hazardous material abatement, demolition of the building, and stabilization of the soil at 49 Center Street. In addition, Mr. Adams will also construct a fence at his own cost. The total cost to Mr. Adams for these actions is approximately $12,000 to $15,000. The City will experience no cost to exchange the property and with evidence of revitalization in the Center Street area this is a positive move forward for both the City and Mr. Adams.

If you have questions or need more information please contact me at 284-9105 or lwaters@biddefordmaine.org. Thank you.

GNECCO LAW OFFICE
215 MAIN ST STE 101 • BIDDEFORD ME 04005

Jeffrey R. Gnecco
Attorney at Law
OFFICE: 207-710-2373
MOBILE: 207-332-9323
EMAIL: jeff@gneccolaw.com

November 14, 2017

Ms. Linda Waters
CDBG Coordinator
City of Biddeford, Maine

Re: 49 Street–57 Pike Street swap

Dear Linda:

In connection with the above-referenced transaction, I hereby certify, on behalf of my client, Daniel Adams, that the following representations are true, having personally reviewed documents in support of the same:

1. The building and property located at 49 Center Street in Biddeford was tested for asbestos in January 2017 under the supervision of Bruce Hackett of Safe Environmental Solutions, Inc., who determined that Vermiculite must be removed from the wall cavities of 49 Center Street prior to demolition building. See attached Asbestos Abatement Cost Proposal from Safe Environmental Solutions, Inc., stating a fixed cost, including DEP reporting, of **$5,235.00.** Asbestos analysis reports from Northeast Laboratory Services and the Zonolite Attic Insulation Trust are attached to the proposal. Mr. Adams will abate the asbestos in accordance with the proposal and applicable law.

2. Post-abatement demolition of the remaining structure, and subsequent fill/grading, is estimated to cost **$4,300.00**. According to Roby Fecteau in the Codes office, "packed reclaim" (i.e., packed dirt) is the appropriate fill material and method for the property. Mr. Adams will comply with the recommendations of the Code office. (As a complete demolition, EPA Renovation, Repair, and Painting regulations do not apply.)

3. Mr. Adams has requested a proposal from Anchor Fence for the fencing along the boundary between 49 and 59 Center Street, but has not received anything in response, though we anticipate no more than **$1,000.00** will be required.

4. The total estimated cost of abatement, demolition, grading, and fencing is estimated to be **$10,535.00**. The total cost of the transaction is estimated to be

$12,000–$15,000. Mr. Adams has financing in place in more than ample amounts to commence and complete the project immediately upon approval by the Council.

The following is a step-by-step outline of the proposed transaction, including the status of all permits and approvals that must be obtained; the cost and source of funds for each step; documents to be prepared, executed, and filed or recorded; construction/demolition work to be completed, and transactions to close.

- Purchase and Sale Agreement and Mutual Release detailing the complete terms of the proposed transactions, to be signed by Daniel Adams as Principal of 59 Center Street LLC and James Bennett, Biddeford City Manager, for the City.
  - Will be drafted by undersigned counsel at Mr. Adams's expense.
  - Order of City Council approving the transaction and authorizing the City Manager to sign the Agreement and all other documents, including deeds, required to complete the transaction, to be sought by the City by timely submission of packet to the City Clerk.
  - Resolution of 59 Center Street LLC authorizing the transaction, to be executed by Daniel Adams as Principal and included in closing binder.
- Certificate of Appropriateness granted by Historic Preservation Commission on 10/12/2017. Copy of decision is attached.
- Asbestos abatement of vermiculite material from 49 Center Street required before demolition, per applicable law.
  - Testing of insulation materials was conducted in January 2017 by Northeast Laboratory Services, and by the Zonolite Attic Insulation Trust. Conclusion: Vermiculite must be removed from the wall cavities of 49 Center Street prior to demolition building. Both reports are attached to the Asbestos Abatement Cost Proposal discussed below.
  - See attached Asbestos Abatement Cost Proposal from Safe Environmental Solutions, Inc., stating a fixed cost, including DEP reporting, of **$5,235.00**
  - See also email correspondence from Zonolite Attic Insulation Trust confirming eligibility for reimbursement of 55% of removal costs, or **$2,879.25.**

  - Abatement shall commence as soon as possible after Council approval is granted.

- Demolition and removal of the building currently standing at 49 Center Street.

- Construction of a suitable 4-ft. chain-link fence along the proposed border separating 49 and 59 Center Street.

- Deed from 59 Center Street LLC to the City conveying 49 Center Street, reserving a seven-foot-wide section along the border with 59 Center Street.

  - Drafted by undersigned counsel at Mr. Adams's expense.

- Deed of Release from the City to 59 Center Street LLC conveying any and all easements, rights-of-way, and other transferable property interests held or asserted by the City in or against the 59 Center Street property, including any property reserved to 59 Center Street LLC from the conveyance of 49 Center Street to the City, and expressly abandoning, waiving, and otherwise relinquishing any and all waivable property rights the City may have by virtue of any statute or other applicable law.

  - Drafted by undersigned counsel at Mr. Adams's expense.

- Release by 59 Center Street LLC of any and all past and present claims or rights of action against the City arising from the design, location, construction, and maintenance of Williams Park, or from access and use of the park by the public.

  - Drafted by undersigned counsel at Mr. Adams's expense.

- Warranty deed from the City to Daniel Adams conveying 57 Pike Street in fee simple for consideration paid, with express release of all claims and encumbrances the City may have against the property on or before the date of the closing.

  - Drafted by undersigned counsel at Mr. Adams's expense.

Please do not hesitate to contact me with any questions.

Sincerely yours,

Jeffrey R. Gnecco, Esq.
Attorney for Daniel Adams

City of Biddeford, Maine
PUBLIC WORKS DEPARTMENT
371 Hill Street, Biddeford, Maine

OCTOBER 23, 2017

Ms. Linda Waters
CDBG Coordinator
City of Biddeford, Maine

Linda :

Included herewith is the metes and bounds description for the proposed conveyance by Daniel Adams to the City of Biddeford for a portion of the property located at 49 Center Street. The description is in accordance with the sketch you provided and per the discussions in our meeting.

It is my understanding that this proposed conveyance is part of a plan that would relocate access to the Williams Court Park from Center Street away from the right of way that is over land of 59 Center Street, LLC. I would point out that should this proposed conveyance be executed it would allow for the construction of an access way to the Williams Court Park but it would not in and of itself eliminate the right of way of record which the City holds over the property of 59 Center Street, LLC. In my opinion, that would require an additional conveyance from the City to 59 Center Street, LLC.

Any questions please feel free to contact me.

Respectfully,

Guy F. Casavant, PLS
Public Works Director
City of Biddeford, Maine

City of Biddeford, Maine
PUBLIC WORKS DEPARTMENT
371 Hill Street, Biddeford, Maine

PROPOSED CONVEYANCE
DANIEL ADAMS
To
CITY OF BIDDEFORD, MAINE

A certain lot or parcel of land situated on the Southerly side of Center Street in the City of Biddeford, County of York, State of Maine, more particularly bounded and described as follows :

Beginning at a drill hole in the sidewalk on the Southerly sideline of Center Street, said drill hole being the Northwesterly corner of land conveyed by Roland L'Heureux to 43 Center Street, LLC by deed dated January 20, 1997 and recorded in the York County Registry of Deeds in Book 16965 Page 493 and being the Northeasterly corner of the herein described parcel;

Thence, Westerly along said Southerly sideline of Center Street, a distance of twelve and twenty-two hundredths (12.22) feet to a point and remaining land of Daniel Adams;

Thence, Southerly along said remaining land of Daniel Adams, a distance of fifty-seven and thirty-seven hundredths (57.37) feet to an iron pipe and land now or formerly of the City of Biddeford, being Parcel #2 in a deed from LASALLE Commercial Mortgage Securities, Inc. Commercial Mortgage Pass-Through Certificates, Series 2006-MF2 dated September 3, 2009 and recorded in the York County Registry of Deeds in Book 15746 Page 130;

Thence, Southeasterly along said land now or formerly of the City of Biddeford, a distance of fifteen and four hundredths (15.04) feet to an iron pipe and other land now or formerly of the City of Biddeford as described in a deed from HSBC Bank USA, National Association by deed dated October 26, 2009 and recorded in the York County Registry of Deeds in Book 15778 Page 99;

Thence, Easterly along said other land now or formerly of the City of Biddeford, a distance of four and sixty-five hundredths (4.65) feet to a drill hole in a granite block and said land now or formerly of 43 Center Street, LLC;

Thence, Northerly along said land now or formerly of 43 Center Street, LLC, a distance of seventy and twenty-eight hundredths (70.28) feet to the Point of Beginning.

Said Parcel contains 812 sq. ft., more or less.

Said Parcel being a portion of the premises conveyed by Gregory F. Clifford to Daniel Adams by deed dated October 6, 2006 and recorded in the York County Registry of Deeds in Book 14978 Page 681.

CITY OF BIDDEFORD
PLANNING DEPARTMENT

Greg D. Tansley, A.I.C.P.
205 Main Street
PO Box 586
Biddeford, ME 04005
(207) 284-9115
Greg.Tansley@biddefordmaine.org

HISTORIC PRESERVATION COMMISSION
REQUEST FOR CERTIFICATE OF APPROPRIATENESS

NOTICE OF DECISION

October 12, 2017

Applicant:	City of Biddeford C/o Linda Waters 205 Main Street Biddeford, ME 04005
File #	2017 HPC.10
Project Address:	49 Center Street Biddeford, ME
Map/Lot:	38/168
Project Zone:	MSRD-1

☐ Contributing ☒ Not Contributing ☐ N/A

Nature of Application:

The applicant proposes the following scope of work:

Demolition of the existing structure.

Findings:

	SUBJECT	*DATA/INFORMATION*
1.	Applicant:	City of Biddeford C/o Linda Waters 205 Main Street Biddeford, ME 04005
2.	Owner of Property:	Dan Adams 49 Center Street Biddeford, ME 04005
3.	Contractor/Developer:	TBD

4.	Project Location:	49 Center Street
5.	Project Tax Map #/Lot #:	Tax Map 38, Lot 168
6.	Existing Zoning:	MSRD-2
7.	Overlay Zoning:	Biddeford Historic District.
8.	Contributing/Non-contributing:	Non-Contributing.
9.	Existing Use:	Vacant Commercial Building
10.	Proposed Use:	Access to Williams Court Park
11.	Proposed Project:	Demolition of entire structure
12.	Approvals Required:	Certificate of Appropriateness
13.	Uses in the Vicinity:	Primarily Residential
14.	Other Permits Obtained:	None
15.	Historic Preservation Commission Review History:	October 11, 2017 Commission Review. The Meeting notice was posted in City Hall 9/29/17; Journal Tribune posting 10/4/17; Mail Notices to all abutters within 100' sent 10/2/17 – 8 notices sent.

Decision:

The Certificate of Appropriateness has been approved conditioned on the materials and assertions presented and:

a. **All permits must be obtained from Code Enforcement prior to beginning any work.**

Thank you for participating in the City of Biddeford's historic preservation efforts.

Sincerely,

Greg D. Tansley, AICP
Biddeford City Planner

Cc: A. Wallach, HPC Chair (via e-mail)
R. Fecteau, Code Enforcement Officer (via e-mail)
D. Charron, Code Enforcement Office Manager (via e-mail)
File

ASBESTOS ABATEMENT COST PROPOSAL
(SES Project 17-01007)

Prepared For:

Mr. Dan Adams
49 Center Street
Biddeford, Maine 04005

At:

49 Center Street
Biddeford, Maine 04005

From:

Bruce M. Hackett, Sr.
Safe Environmental Solutions, Inc.
62 Darling Avenue
South Portland, Maine 04106

January 19, 2017

We appreciate the opportunity to assist you with your Asbestos Abatement Needs. This letter is in response to the asbestos abatement of the Vermiculite located in the wall cavities of your center street building which needs to be removed prior to demolition of the facility. The removal will be completed under the State of Maine, Federal EPA and OSHA requirements.

Breakdown of Costs:

Base Bid – Asbestos floor tile removal

➢ Labor, Materials, Waste	$4,750.00
➢ DEP Notification filing fees & Independent Visual & Air Clearance (DEP required)	$485.00
	$5,235.00

I trust this information is sufficient for your asbestos abatement planning needs. We look forward to serving you and stand committed to a safe and healthful Maine environment. Our payment terms are net due upon completion. Should you have any further questions or concerns please feel free to contact me.

Sincerely

Sincerely,

Bruce M. Hackett, Sr.
Bruce M. Hackett, Sr.
President

In signing below you are agreeing to the cost and our payment terms with is NET due upon completion of the removal. Thank-you for your business. We are currently booking 2 weeks out. Thank-you for the opportunity.

_____ _____

Mr. Dan Adams Date

Northeast Laboratory Services
P.O. Box 788
Waterville, Maine 04903-0788

199 Forest Avenue
Portland, Maine 04103

ASBESTOS ANALYSIS

Report Date: January 13, 2017

Received Date: 1/10/2017

Administrative Offices
Phone : 207-873-7711
Fax : 207-873-7022

Customer Service
Phone : 207-878-6481
Fax : 207-878-2265

CLIENT
Dan Adams
64 Pike St
Biddeford ME 04005

Analysis Report of Bulk Material via EPA Method 600/R-93/116 Polarized Light Microscopy

SAMPLE ID	Project Number	Project Name	Color	Non-Asbestos Fibrous	Non-Fibrous	Asbestos
RD00119	49 Center St		Black	-- %	04 %	Not Detected
Client ID/Desc: Black Armstrong Tile		**Analyzed Date** 1/13/2017	**Test:** PLM NOB			**Analyst** ASM
RD00120	49 Center St		Brown	-- %	67 %	Not Detected
Client ID/Desc: Brown Shingle		**Analyzed Date** 1/13/2017	**Test:** PLM NOB			**Analyst** ASM

Should you have any questions concerning your asbestos test result(s), please feel free to call us. Thank you for using Northeast Laboratory testing services. Contact NEL for your other environmental analytical needs, including water testing for lead and arsenic or indoor air quality.

Authorized by: Bill Sargent, Laboratory Manager **Date:** 1/13/2017

Subject: RE: W.R. Grace ZAI Trust- Sample Results [Options] From: Jillian Colley <JColley@zaitrust.com> [Options] To: "adams.dan@usa.net" <adams.dan@usa.net>

Good Afternoon,

Recently, you sent us a vermiculite sample to have analyzed to see if you qualify for reimbursement from the Zonolite Attic Insulation Trust ( ). As with all sent samples, it was analyzed for barium content to determine if it was consistent with vermiculite mined in Libby, MT. IT WAS NOT ANALYZED FOR THE PRESENCE OR ABSENCE OF ASBESTOS. Your sample came back CONSISTENT, suggesting that the vermiculite was mined in Libby, MT and is therefore Zonolite Attic Insulation. Your claim is now considered to meet the product identification requirement.

The second requirement for your claim is to finalize the claim form that you started online as well as complete the removal and replacement, or containment requirements for the claim and provide the necessary documentation. Please supply proof of removal or containment and payment for the removal in the form of a copy of the canceled check, bank statement or credit card statement. You may send the requested proof to me by e-mail, fax or regular mail. You may also submit re-insulation costs if you wish. The Trust could reimburse you 55% of removal and re-insulation costs with a maximum claim amount being $7,500.00. So the most that you could expect to receive back would be 55% of $7,500.00, which is $4,125.00.

Thank you so much for your patience, if you have already submitted this information, we will be sure to provide an update of your claim in 30 days.

Happy Holidays!

Jillian N. Colley
ZAI Trust
317 Wingo Way, Suite 303, Mt. Pleasant, SC 29464
P: (843) 388-4321 | Toll-free: (844) 924-2255
F: (843) 388-3790 |

Peter Petit Excavating, Inc.
61 Harding Street
Biddeford, ME 04005 - 3833
Tel: 207 282-9305

ESTIMATE

Name / Address
Dan Adams 59 Center Street Biddeford, ME 04005

Date	Estimate #
1/20/2017	1228

Item	Description	Total
	42 Center Street	
Demo	Demo building	3,500.00
Grade	Grade, stabilize	800.00
	Note: you will need to get a demo permit & there are a few DEP forms to be filled out through the code office I can take care of that for you if you want	
	Total	$4,300.00

Property Location: 49 CENTER ST | **MAP ID:** 38/ 168/ / / | **Bldg Name:** | **State Use:** 3220
Vision ID: 4175 | **Account #** | **Bldg #:** 1 of 1 | **Sec #:** 1 of 1 | **Card** 1 of 1 | **Print Date:** 08/16/2017 13:32

CURRENT OWNER	TOPO.	UTILITIES	STRT./ROAD	LOCATION
ADAMS, DANIEL	1 Level	3 Public Sewer	1 Paved	4 Bus. District
64 PIKE ST		2 Public Water	5 Curb & Gutter	
BIDDEFORD, ME 04005			6 Sidewalk	
Additional Owners:				

SUPPLEMENTAL DATA

Other ID:		Color	NATURAL/TAN
Sub-Div		H. District	136
Photo		S. District	4
Ward	5	TIF	
Prec.	DBID		
Tract	CO	ASSOC PID#	
GIS ID: 38-168			

CURRENT ASSESSMENT

Description	Code	Appraised Value	Assessed Value
COMMERC.	3220	13,500	13,500
COM LAND	3220	46,400	46,400
		Total	59,900	59,900

4505 BIDDEFORD, ME

VISION

RECORD OF OWNERSHIP	BK-VOL/PAGE	SALE DATE	q/u	v/i	SALE PRICE	V.C.
ADAMS, DANIEL	14978/ 681	10/06/2006	Q	I	60,000	00
CLIFFORD GREGORY F	02186/0011	05/03/1977			0	

PREVIOUS ASSESSMENTS (HISTORY)

Yr.	Code	Assessed Value	Yr.	Code	Assessed Value	Yr.	Code	Assessed Value
2016	3220	14,800	2015	3220	14,800	2014	3220	14,800
2016	3220	33,400	2015	3220	33,400	2014	3220	33,400
		Total: 48,200			Total: 48,200			Total: 48,200

EXEMPTIONS

Year	Type	Description	Amount
		Total:	

OTHER ASSESSMENTS

Code	Description	Number	Amount	Comm. Int.

This signature acknowledges a visit by a Data Collector or Assessor

ASSESSING NEIGHBORHOOD

NBHD/ SUB	NBHD Name	Street Index Name	Tracing	Batch
0003/A				

NOTES

THE DRIVING SCHOOL
ONLY 3/4 PARTITION AROUND
TOILET
FUNC=SIZE/PARKING
2.00 -30 SIZE/TOPO

CERT #1095, 1129

APPRAISED VALUE SUMMARY

Appraised Bldg. Value (Card)	13,500
Appraised XF (B) Value (Bldg)	0
Appraised OB (L) Value (Bldg)	0
Appraised Land Value (Bldg)	46,400
Special Land Value	0
Total Appraised Parcel Value	59,900
Valuation Method:	C
Exemptions	0
Adjustment:	0
Net Total Appraised Parcel Value	59,900

BUILDING PERMIT RECORD

Permit ID	Issue Date	Type	Description	Amount	Insp. Date	% Comp.	Date Comp.	Comments
09-06-322	06/05/2009	RE	Remodel	0	09/01/2009	100	04/01/2010	INSTALLATION OF SE
08-11-216	11/15/2007	CM	Commercial	0	07/14/2008	100	04/01/2008	FACADE SIGN

VISIT/ CHANGE HISTORY

Date	Type	IS	ID	Cd.	Purpose/Result
09/01/2009	02		ND	03	Outside inspection only
07/14/2008	02		ND	03	Outside inspection only
01/11/2002			FY	28	COMM/ IND/APTS 2002-
01/11/1990			SC	00	MEAS & LISTD

LAND LINE VALUATION SECTION

B #	Use Code	Use Description	Zone	D	Front	Depth	Units		Unit Price	I. Factor	S.A.	Acre Disc	C. Factor	ST. Idx	Adj.	Notes- Adj	Special Pricing	S Adj Fact	Adj. Unit Price	Land Value
1	3221	STORE/SHOP MDL-96	ISRD				1,238	SF	30.01	2.5000	X	1.0000	0.50	0003	1.00	SIZE, LOP		1.00	37.51	46,400
Total Card Land Units:							0.03	AC	Parcel Total Land Area: 0.03 AC										Total Land Value:	46,400

Property Location: 49 CENTER ST
Vision ID: 4175
Account #
MAP ID: 38/ 168/ / /
Bldg Name:
Bldg #: 1 of 1 **Sec #:** 1 of 1 **Card** 1 **of** 1
State Use: 3220
Print Date: 08/16/2017 13:32

CONSTRUCTION DETAIL

Element	Cd.	Ch.	Description
Style	18		Office Bldg
Model	96		Industrial
Grade	01		Minimum
Stories	1		
Occupancy	1		
Exterior Wall 1	14		Wood Shingle
Exterior Wall 2			
Roof Structure	03		Gable/Hip
Roof Cover	03		Asph/F Gls/Cmp
Interior Wall 1	04		Plywood Panel
Interior Wall 2			
Interior Floor 1	14		Carpet
Interior Floor 2			
Heating Fuel	03		Gas
Heating Type	03		Hot Air-no Duc
AC Type	01		None
Bldg Use	322I		STORE/SHOP MDL-96
Total Rooms			
Total Bedrms	00		
Total Baths	2		
Heat/AC	00		NONE
Frame Type	02		WOOD FRAME
Baths/Plumbing	02		AVERAGE
Ceiling/Wall	05		SUS-CEIL & WL
Rooms/Prtns	01		LIGHT
Wall Height	10		
% Comn Wall	0		

CONSTRUCTION DETAIL (CONTINUED)

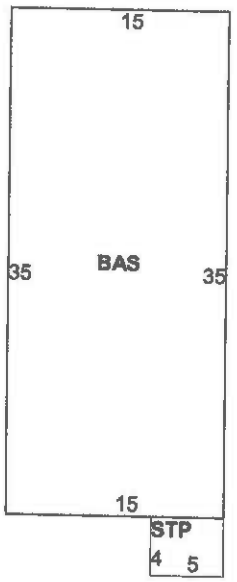
Element	Cd.	Ch.	Description

MIXED USE

Code	Description	Percentage
322I	STORE/SHOP MDL-96	100

COST/MARKET VALUATION

Adj. Base Rate:	61.20
Net Other Adj:	0.00
AYB	1930
EYB	1990
Dep Code	F
Remodel Rating	
Year Remodeled	
Dep %	48
Functional Obslnc	10
External Obslnc	0
Cost Trend Factor	1
Condition	
% Complete	
Overall % Cond	42
Apprais Val	13,500
Dep % Ovr	0
Dep Ovr Comment	
Misc Imp Ovr	0
Misc Imp Ovr Comment	
Cost to Cure Ovr	0
Cost to Cure Ovr Comment	



OB-OUTBUILDING & YARD ITEMS(L) / XF-BUILDING EXTRA FEATURES(B)

Code	Description	Sub	Sub Descript	L/B	Units	Unit Price	Yr	Gde	Dp Rt	Cnd	%Cnd	Apr Value

BUILDING SUB-AREA SUMMARY SECTION

Code	Description	Living Area	Gross Area	Eff. Area	Unit Cost	Undeprec. Value
BAS	First Floor	525	525	525	61.20	32,130
STP	Stoop	0	20	2	6.12	122
	Tl. Gross Liv/Lease Area:	525	545	527		

Property Location: 57 PIKE ST
Vision ID: 4745
Account #
MAP ID: 39/ 274/ / /
Bldg #: 1 of 1
Bldg Name:
Sec #: 1 of 1 Card 1 of 1
State Use: 9035
Print Date: 02/18/2016 16:16

CURRENT OWNER	TOPO.	UTILITIES	STRT./ROAD	LOCATION
CITY OF BIDDEFORD	4 Rolling	3 Public Sewer	1 Paved	1 Urban
PO BOX 586		2 Public Water	5 Curb & Gutter	
BIDDEFORD, ME 04005			6 Sidewalk	
Additional Owners:				

SUPPLEMENTAL DATA

Other ID:	Color
Sub-Div	H. District 136
Photo	S. District 4
Ward 2	TIF
Prec.	
Tract 3F	
GIS ID: 39-274	ASSOC PID#

CURRENT ASSESSMENT

Description	Code	Appraised Value	Assessed Value
EXM LAND	9035	33,300	33,300
		Total	33,300	33,300

4505
BIDDEFORD, ME

VISION

RECORD OF OWNERSHIP	BK-VOL/PAGE	SALE DATE	q/u	v/i	SALE PRICE	V.C.
CITY OF BIDDEFORD	COUNCL ORDR	04/06/2010	U	V		1K
GOULETTE, GREGORY J	05960/0136	02/04/1992	U	I	25,000	IN
WEST COAST	05764/0255	07/12/1991	U	I	0	1B
LONE STAR	05680/0084	04/19/1991	U	I	0	1L
FOAV INC	05220/0115	10/19/1989	U	I	1,820,000	1N

PREVIOUS ASSESSMENTS (HISTORY)

Yr.	Code	Assessed Value	Yr.	Code	Assessed Value	Yr.	Code	Assessed Value
2015	9035	33,300	2014	9035	33,300	2013	9035	37,900
		Total: 33,300			Total: 33,300			Total: 37,900

EXEMPTIONS

Year	Type	Description	Amount
		Total:	

OTHER ASSESSMENTS

Code	Description	Number	Amount	Comm. Int.

This signature acknowledges a visit by a Data Collector or Assessor

APPRAISED VALUE SUMMARY

Appraised Bldg. Value (Card)	0
Appraised XF (B) Value (Bldg)	0
Appraised OB (L) Value (Bldg)	0
Appraised Land Value (Bldg)	33,300
Special Land Value	0
Total Appraised Parcel Value	33,300
Valuation Method:	C
Exemptions	0
Adjustment:	0
Net Total Appraised Parcel Value	33,300

ASSESSING NEIGHBORHOOD

NBHD/ SUB	NBHD Name	Street Index Name	Tracing	Batch
0003/A				

NOTES

SUPPLEMENT WITH WARRANT
1996
INCREASE IN LAND VALUE
AUTHORITY (17 MRSA 2853)

BUILDING PERMIT RECORD

Permit ID	Issue Date	Type	Description	Amount	Insp. Date	% Comp.	Date Comp.	Comments
96-7-209	07/17/1996	DE	Demolish	0	04/22/1997	100	04/01/1997	DEMO/BUIL

VISIT/ CHANGE HISTORY

Date	Type	IS	ID	Cd.	Purpose/Result
01/15/2016	02		ND	03	Outside inspection only
01/01/2004			FY	36	UPDATE LAND CURVE
04/22/1997			FY	19	DC 1997 UPDATE
12/19/1989	X		CR	02	Left Hanger

LAND LINE VALUATION SECTION

B #	Use Code	Use Description	Zone	D	Front	Depth	Units		Unit Price	I. Factor	S.A.	Acre Disc	C. Factor	ST. Idx	Adj.	Notes- Adj	Special Pricing		S Adj Fact	Adj. Unit Price	Land Value
																	Spec Use	Spec Calc			
1	9035	TOWN-PROP MDL-00	R2				12,197	SF	4.33	0.7000	3	1.0000	0.90	0003	1.00				1.00	2.73	33,300

Total Card Land Units: 0.28 AC Parcel Total Land Area: 0.28 AC Total Land Value: 33,300

Property Location: 57 PIKE ST
Vision ID: 4745
Account #
MAP ID: 39/ 274/ / /
Bldg #: 1 of 1
Bldg Name:
Sec #: 1 of 1
Card 1 of 1
State Use: 9035
Print Date: 02/18/2016 16:16

CONSTRUCTION DETAIL

Element	Cd.	Ch.	Description
Model	00		Vacant

CONSTRUCTION DETAIL (CONTINUED)

Element	Cd.	Ch.	Description

MIXED USE

Code	Description	Percentage
9035	TOWN-PROP MDL-00	100

COST/MARKET VALUATION

Adj. Base Rate:	0.00
Net Other Adj:	0.00
AYB	
EYB	0
Dep Code	
Remodel Rating	
Year Remodeled	
Dep %	
Functional Obsinc	
External Obsinc	
Cost Trend Factor	1
Condition	
% Complete	
Overall % Cond	
Apprais Val	
Dep % Ovr	0
Dep Ovr Comment	
Misc Imp Ovr	0
Misc Imp Ovr Comment	
Cost to Cure Ovr	0
Cost to Cure Ovr Comment	

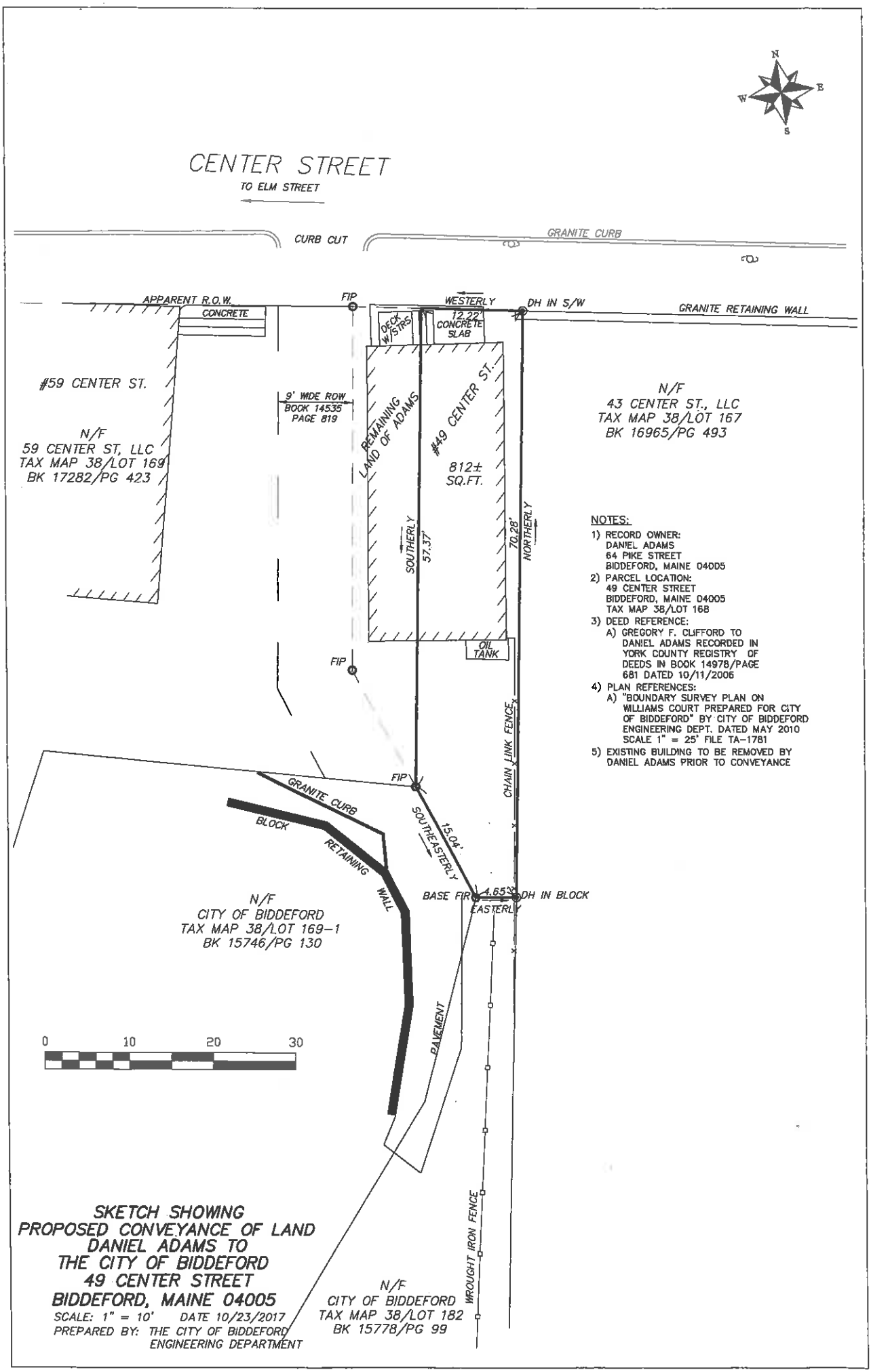
OB-OUTBUILDING & YARD ITEMS(L) / XF-BUILDING EXTRA FEATURES(B)

Code	Description	Sub	Sub Descript	L/B	Units	Unit Price	Yr	Gde	Dp Rt	Cnd	%Cnd	Apr Value

BUILDING SUB-AREA SUMMARY SECTION

Code	Description	Living Area	Gross Area	Eff. Area	Unit Cost	Undeprec. Value
	Tot. Gross Liv/Lease Area:	0	0	0		

No Photo On Record



NOTES:

1) RECORD OWNER:
DANIEL ADAMS
64 PIKE STREET
BIDDEFORD, MAINE 04005
2) PARCEL LOCATION:
49 CENTER STREET
BIDDEFORD, MAINE 04005
TAX MAP 38/LOT 168
3) DEED REFERENCE:
A) GREGORY F. CLIFFORD TO DANIEL ADAMS RECORDED IN YORK COUNTY REGISTRY OF DEEDS IN BOOK 14978/PAGE 681 DATED 10/11/2006
4) PLAN REFERENCES:
A) "BOUNDARY SURVEY PLAN ON WILLIAMS COURT PREPARED FOR CITY OF BIDDEFORD" BY CITY OF BIDDEFORD ENGINEERING DEPT. DATED MAY 2010 SCALE 1" = 25' FILE TA-1781
5) EXISTING BUILDING TO BE REMOVED BY DANIEL ADAMS PRIOR TO CONVEYANCE

SKETCH SHOWING
PROPOSED CONVEYANCE OF LAND
DANIEL ADAMS TO
THE CITY OF BIDDEFORD
49 CENTER STREET
BIDDEFORD, MAINE 04005

SCALE: 1" = 10' DATE 10/23/2017
PREPARED BY: THE CITY OF BIDDEFORD
ENGINEERING DEPARTMENT

2018.9 IN BOARD OF CITY COUNCIL..JANUARY 2, 2018

RESOLUTION AUTHORIZING THE CITY TO JOIN A LAWSUIT AGAINST OPIATE DRUG COMPANIES

WHEREAS, the City Council of Biddeford, Maine, has learned to its sorrow over the last several years exactly how devastated many of its residents have become because of addictions to painkillers manufactured by drug companies; and

WHEREAS, officers working for the Biddeford Police Department, Fire Department and several other City Departments are required to respond every day to problems that arise because of addiction to painkillers; and

WHEREAS, to treat and abate the opioid epidemic, the City has needed to shift resources that could have otherwise been used for various improvements and the general betterment of the City;

WHEREAS, employees who manage social services work with many people who suffer from drug addiction to painkillers and who struggle to care for themselves; and

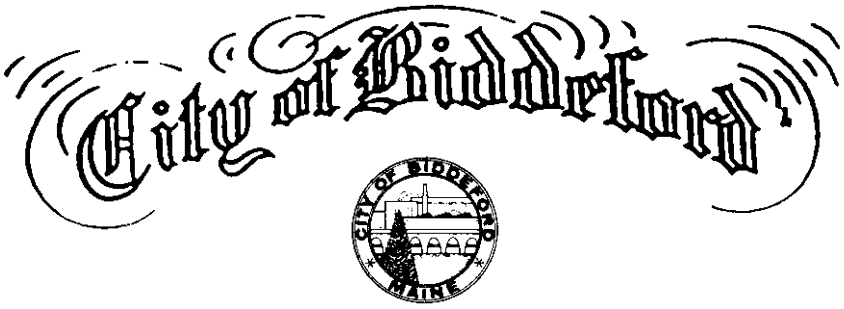
WHEREAS, approximately 80 percent of people who use heroin have been prescribed opiates in the past; and

WHEREAS, in 2016, 376 people died in the State of Maine from drug overdoses, and 123 of those deaths were caused by pharmaceutical opioids; and

WHEREAS, the ease with which these drugs have been obtained, as a result of drug companies' campaign to make them readily prescribed for common aches and pains, has led many people to become addicted; and

WHEREAS, opiate drug companies have enjoyed enormous profits with the sales of opiate drugs, promoting them relentlessly among physicians and paying doctors to promote these drugs at conferences, while failing repeatedly to successfully tailor the drugs to make abuse impossible;

NOW, THEREFORE, BE IT RESOLVED, that the Biddeford City Council and Mayor hereby authorize the City Manager to engage the services of Napoli Shkolnik, PLLC and Trafton, Matzen, Belleau & Frenette, LLP on behalf



of the City of Biddeford with respect to prosecution of any legal claims against manufacturers and distributors of opioids arising out of the manufacturers' and distributors' fraudulent and negligent marketing and distribution of opioids.

NAPOLI SHKOLNIK PLLC
ATTORNEYS AT LAW

THIS CONTRACT IS SUBJECT TO ARBITRATION UNDER THE FEDERAL ARBITRATION ACT

LEGAL SERVICES CONTRACT

Mail or Fax to:

NAPOLI SHKOLNIK PLLC
Attn: Paul Napoli, Esq.
360 Lexington Avenue, 11th Floor
New York, NY 10017
Telephone: (212) 397-1000
Fax: (646) 843-7603

TRAFTON, MATZEN, BELLEAU & FRENETTE, LLP
Attn: James Belleau, Esq.
Ten Minot Avenue
P.O. Box 470
Auburn, Maine 04212-0470
Telephone: (207) 784-4531
Fax: (207) 784-8738

WHEREAS, the undersigned ("Client") agrees to retain the law offices of Napoli Shkolnik PLLC and Trafton, Matzen, Belleau, & Frenette, LLP) ("Law Firms") (collectively, "Parties") as Client's attorneys in the prosecution of any legal claim against manufacturers and distributors of opioids arising out of the manufacturers' and distributors' fraudulent and negligent marketing and distribution of opioids. The Parties specifically agree as follows:

1. **FEE PERCENTAGE:** As consideration for legal services rendered and to be rendered by the Attorneys in carrying out the purpose hereof, Client agrees to pay Law Firm 25% (twenty-five percent) of all net amounts recovered. Further, if the action is certified as a class action, the law firm shall request an award of common benefit fees and compensation to be awarded within the discretion of the court irrespective of the stated retainer amount. Client assigns, and the Law Firm accepts and acquires as its fee, a proportionate interest in the subject matter of any claim, action, or suit instituted or asserted under the provisions of this agreement. All expenses and costs will be deducted prior to the contingent fee calculation to the extent there is a recovery on the claim in question. To be clear, Client is only obligated to repay costs and expenses to the extent there is a recovery on the claim in question. Any liens and subrogation are to be deducted after the contingent fee is calculated.

2. **DISBURSEMENTS:** The Law Firm shall be reimbursed all reasonable expenses associated with the legal services being rendered including, but not limited to, legal research, long distance telephone calls, fax, postage, copying, travel, litigation, and expert expenses. Costs shall also include, but not be limited to, any "MDL Assessment" imposed by any Multi-

District Litigation ("MDL") Court or withheld from any settlement or favorable judgment by any defendant. In addition to the above listed individual costs, there will be common benefit costs. Common benefit costs are costs expended for the common benefit of a group of clients. For example, if a deposition of a defendant expert witness is taken in one case, and this deposition can be used for and/or benefits the claims of many other clients, these costs will be classified as common benefit costs. By using this common benefit cost system, no one client has to solely bear the costs which actually benefit the group as a whole, and many of the most substantial costs of litigation can be shared equally by all. Client grants a special privilege to the Law Firm for their professional fees, expenses, costs, interest, and loans, on all monies and properties recovered or obtained for Client. Client's repayment of costs and expenses is contingent on the outcome from any funds received on the claim in question. To be clear, Client is only obligated to repay costs and expenses to the extent there is a recovery on the claim in question.

3. **FINANCING OF CASE:** If the firm borrows money from any lending institution to finance the cost of the client's case, the amounts advanced by this firm to pay the cost of prosecuting or defending a claim or action or otherwise protecting or promoting the client's interest will bear interest at the highest lawful rate allowed by applicable law. In no event will the interest be greater than the amount paid by the firm to the lending institution.

4. **TAX ADVICE:** The Client understands that the Law Firm will not provide any advice regarding the tax consequences of accepting money from a settlement or award. CLIENT SHOULD CONTACT A TAX PROFESSIONAL REGARDING ANY TAX CONCERNS REGARDING ANY SETTLEMENT PRIOR TO THE SETTLEMENT.

5. **TERMINATION:** The Law Firm expressly reserves the right to withdraw its representation at any time upon reasonable notification to the Client, subject to applicable ethical rules, if any. Should the Client terminate the Law Firm, the Law Firm shall continue to be entitled to its legal fees on any and all sums recovered as a result of the claims.

6. **APPEALS:** The above contingency fee does not contemplate any appeal. The Law Firm is under no duty to perfect or prosecute any such appeal until a satisfactory fee arrangement is made between the Parties and is reduced to writing regarding costs and attorneys' fees.

7. **COUNTERCLAIMS:** The above contingency fee does not contemplate the Law Firm's representation of Client against any claims made by a person against the Clients. The Law Firm is under no duty to defend or prosecute any such claim or counterclaim until a satisfactory fee arrangement is made between the Parties and is reduced to writing regarding costs and attorneys' fees.

8. **STATUTE OF LIMITATIONS:** Client understands that the Statute of Limitations period for the case must be investigated and that this Agreement is made subject to that investigation as well as an investigation of the entire case. Client understands that statutes

of limitation may have run on the case and agrees to hold the Law Firm harmless in the event the applicable statutes of limitation have run for any reason.

9. **NO GUARANTEE OF FINAL OUTCOME:** No attorney can accurately predict the outcome of any legal matter. Accordingly, the Law Firm makes no express or implied representations as to the final outcome of the matter(s) contemplated by this Agreement. Client further understands that Client must immediately report any changes in Client's address or telephone number to the Law Firm.

10. **APPROVAL NECESSARY FOR SETTLEMENT:** Client hereby grants the Law Firm power of attorney so that the Law Firm may have full authority to prepare, sign and file all legal instruments, pleadings, drafts, authorizations, and papers as shall be reasonably necessary to conclude the representation including settlement and/or reducing to possession any and all monies or other things of value due to Client under its claim as fully as the Client could do so. The Law Firm is also authorized and empowered to act as Client's sole negotiator in any and all negotiations concerning the subject of this Agreement. To be clear, all decisions regarding final resolution of the litigation, including settlement, are within the sole power of the Client.

11. **ASSOCIATION OF OTHER ATTORNEYS:** The Law Firm may, at its own expense, use or associate with other attorneys in the representation of the Client. Client understands that the Law Firm is a Professional Limited Liability Company with a number of attorneys. Several of those attorneys may work on Client's case.

12. **ASSOCIATE COUNSEL:** Another attorney may participate in the division of fees in this case and assume joint responsibility for the representation of Client, either in the event that the Law Firm retains associate counsel or in the event that Client later chooses new counsel, provided that the total fee to Client does not decrease as a result of the division of fees and that the attorneys involved have agreed to the division of fees and assumption of joint responsibility.

13. **CLASS ACTION:** Client understands that Attorneys may pursue a class action on behalf of Client and all others similarly situated and client specifically authorizes attorneys to do so. Client understands that Client may serve as a class representative and may be called upon to act in a representative capacity for those who are similarly situated. Client knows of no conflict that would cause Client to be inadequate representative and agrees to vigorously defend the interests of the class if called upon to do so.

14. **MAINE STATE LAW TO APPLY:** This Agreement shall be construed under and in accordance with the laws of the State of Maine, and the rights, duties and obligations of Client and of the Law Firm's representation of Client and the laws of the State of Maine shall govern regarding anything covered by this Agreement.

NAPOLI SHKOLNIK PLLC
ATTORNEYS AT LAW

15. **ARBITRATION:** Any and all disputes, controversies, claims or demands arising out of or relating to (i) this Agreement; (ii) any provision of this Agreement; (iii) the provision of services by the Law Firm to Client; and (iv) the relationship between the Parties, whether in contract, tort or otherwise, at law or in equity, for damages or any other relief, shall be resolved by binding arbitration pursuant to the Federal Arbitration Act in accordance with the Commercial Arbitration Rules then in effect with the American Arbitration Association. Client shall not file a class action against at the Law Firm or seek to assert any claims or demands against the Law Firm by or through a class action, either as the named plaintiff or as a member of the class, but rather shall submit his/her claims or demands to binding arbitration. Any such arbitration proceeding shall be conducted in Maine. This arbitration provision shall be enforceable in either federal or state court in Maine, pursuant to the substantive federal laws established by the Federal Arbitration Act. Any party to any award rendered in such arbitration proceeding may seek a judgment upon the award and any Court in Maine having jurisdiction may enter that judgment.

16. **PARTIES BOUND:** This Agreement shall be binding upon and inure to the benefit of the Parties hereto and there respective heirs, executors, administrators, legal representative, successors and assigns.

17. **LEGAL CONSTRUCTION:** In case any one or more of the provisions contained in this Agreement shall for any reason be held invalid, illegal or unenforceable, such invalidity, herein illegality, or unenforceability shall not affect any other provisions hereof, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provision had never been contained.

18. **PRIOR AGREEMENTS SUPERSEDED:** This Agreement constitutes the sole and only agreement of the Parties hereto and supersedes all prior understandings or written or oral agreement between the Parties respecting the within subject matter, if any.

Client certifies and acknowledges that Client has had the opportunity to read this Agreement. Client further affirms that Client has voluntarily entered into this Agreement, that Client has been advised that Client may seek legal counsel to review this Agreement before signing, and that Client is fully aware of the terms and conditions contained in this Agreement.

SIGNED AND ACCEPTED ON THIS _____day of_____, 2018

THIS CONTRACT IS SUBJECT TO ARBITRATION UNDER THE FEDERAL ARBITRATION ACT	
Print Client's Name: Biddeford, Maine	**Napoli Shkolnik PLLC**
Signature:	**By:**

Address:	**TRAFTON, MATZEN, BELLEAU & FRENETTE, LLP**
	By:


NAPOLI
SHKOLNIK PLLC
ATTORNEYS AT LAW
2017 LEGAL REPORT
NAPOLILAW.COM

We hope you find this informative and look forward to working alongside you.

NAPOLI SHKOLNIK PLLC
ATTORNEYS AT LAW

360 LEXINGTON AVENUE, 11TH FLOOR
NEW YORK, NEW YORK 10017

(212) 397-1000
NAPOLILAW.COM

Photography by Kasia Bialasiewicz, Emanuele Bresciani, Albert Cheung, Chris L, Evan Sung and Bigstock: Corepics, curaphotography, Flynt, gvictoria, Levent, Maarigard, Konuk, Sushytska, Tomaxz Gierygowski, udon10671, wayne0216.

Contents

FROM RIGHT
Hunter J. Shkolnik, Partner, Marie Napoli, Partner, and Paul J. Napoli, Of Counsel.

Our Mission

is to help families cope with their loss by compassionately caring for their legal needs.

We attentively persist to achieve the best possible outcome for our clients and provide unparalleled level of service.

We accomplish this by fostering a confident client focused work environment of motivated employees where cooperation thrives and innovation is rewarded.

How Can We Help?

Our clients come from across the United States. We work alongside local co-counsel all over the country.

We evaluate cases daily and we

encourage you to contact Napoli Shkolnik PLLC to discuss steps for compensation for our clients as well as to speak about any new litigations.

Our attorneys hold a variety of leadership positions (lead or liaison counsel, members of litigation steering committees) in numerous multi-district litigations for pharmaceutical cases and class actions..

We have active offices in California, Delaware, Florida, Illinois (Madison County and Chicago), New Jersey, Pennsylvania, Texas and our principal offices are in New York City and Long Island.

Interested parties call

(212) 397-1000

Asbestos Related Illness

Aviation Accidents

Civil Rights

Complex Litigation

Defective Medical Devices

Defective Prescription Drugs

Class Actions

Environmental Litigation

Medical Malpractice

Personal Injury

Social Security Disability

Workers' Compensation

World Trade Center

We look forward to building a mutually beneficial relationship together.

Team Profiles

Napoli Shkolnik PLLC is a national litigation firm representing victims of defective prescriptions drugs and medical devices, asbestos-related illnesses, aviation accidents, complex litigation and other serious personal injury matters.

Marie Napoli

Partner

Bar Admissions

New York

United States Supreme Court

New York Supreme Court

United States District Court, Eastern District of New York

United States District Court, Southern District of New York

History

Notes & Comments Editor, *St. John's Journal of Legal Commentary*

Notes & Comments Editor, *St. Mary's Law Journal*

President, St. John's Alumni Association, Nassau Chapter

Vice President, Friend's Academy Parent Council

Board Member, Glen Cove Boys & Girls Club

Affiliations

American Association for Justice

New York State Trial Lawyers Association (Board of Directors)

New York State Academy of Trial Lawyers

New York State Bar Association

New York Women's Bar Association

The Bone Marrow Foundation (Associate Board Member)

Publications

The Lord in the Law

Reflections on a Catholic Law School, St. Mary's Law Review

He Said, She Said, St. John's Journal of Legal Commentary

Marie Napoli has over twenty years of experience handling personal injury, medical malpractice, mass tort, and complex litigation matters.

She is one of the few female partners in a top mass tort litigation firm with a successful and proven track record. She has worked for the New York Appellate Division, 2nd Department and has taught CLE courses on Tort & Civil Procedure at St. John's University School of Law.

As a founding partner of Napoli Kaiser Bern LLP, Marie was involved in many high level negotiations that resulted in favorable settlements for their clients. Notably, Marie was part of the team responsible for the billion dollar settlement in a major pharmaceutical case.

Marie understands the breadth of the legal issues that particularly affect women injured by pharmaceutical and other defective products. She is a breast cancer survivor and philanthropist. She channels her passion to create awareness and fund research through such organizations and events as The Bone Marrow Foundation, Inc., the Long Island Half Marathon and the New York City Marathon.

Full bio › **goo.gl/Uw45u1**

Hunter J. Shkolnik

Partner

Hunter J. Shkolnik concentrates his area of practice to the trial of significant personal injury cases primarily in the area of drug, automobile, heavy truck and aviation related product liability actions.

He leads the discovery and trial teams of various mass tort pharmaceutical and medical device litigations for the firm. He is also active in managing national litigation and plaintiff litigation groups including the American Association of Justice's Actos Litigation Group.

He is currently serving as a chairman, leader or court appointed representative on Plaintiff Steering Committees in various drug and other mass torts. Additionally Mr. Shkolnik has also held officer positions in the New York State Trial Lawyers, Nassau County Bar Association and Committee Chair positions in ATLA Health Care Finance Litigation Group, Orthopedic Implant Litigation Group, AAJ Breast Cancer Litigation Group, Co-Chair AAJ Heart Device Litigation Group and the Chair of the Medtronic ICD and CRTD Litigation Sub Group.

Mr. Shkolnik has also lectured and organized seminars on issues involving Guidant, Medtronic and St. Jude pacemakers, ICD and Lead Wire recall science and litigation; Cardiac Device product liability litigation, Class Actions topics such as Ethics of Mass Tort Settlements, Lone Pine, State Federal Coordination and Preemption and on multiple occasions, on science related to various pharmaceuticals.

Full bio › goo.gl/LJX3FJ

Bar Admissions

New York

United States District Court, Eastern District of New York

United States District Court, Southern District of New York

New Jersey

United States District Court, District of New Jersey

Honors

New York Super Lawyers (2006–2017)

Publications

Sikkelee: A Victory for Plaintiffs and its Implications for Aviation Product Liability Claims, American Association for Justice Aviation Law Newsletter, Winter 2017

Danger in the Ring by Marie Brenner, *Vanity Fair,* January 2014

Divided They Fall: Concepcion's Effect on Consumer and Employee Claims (Co-Author: Richard J. Arsenault, Esq.), NYSTLA, Vol. 1, 2012

Affiliations

American Association of Justice (AAJ), The Actos Bladder Cancer Litigation Group, Co-Chair

Litigation Counsel of America, Fellow

New York State Trial Lawyers (NYSTLA), Board of Directors; Past Secretary, Assistant Treasurer and Treasurer

Long Island Affiliate of the NYSTLA, Past President

Nassau County Bar Association, Past Vice-Chairman, Medical Legal Committee

AAJ, Past Vice-Chairman, Healthcare Finance Litigation Group

AAJ Health Orthopedic Implant Litigation Group, Past Vice-Chairman, Science Committee Director

AAJ, Past Chairman, Health Breast Cancer Litigation Group

AAJ, Co-Chair, Health Heart Device Litigation Group

Paul J. Napoli

Of Counsel

Bar Admissions

New York

United States District Court, Eastern District of New York

United States District Court, Southern District of New York

United States District Court, Northern District of New York

New York State Court, Appellate Division Second Judicial Dept.

United States Court of Appeals for the Second Circuit

United States Court of Appeals for the Third Circuit

Illinois

United States Supreme Court

Honors

Lawyers of Distinction, 2016

Litigator Award, 2015

Litigation Counsel of America, The Trial Lawyer Honorary Society, Senior Fellow

Legal Leaders, Martindale-Hubbell Top Rated Lawyers, 2014 & 2015

Affiliations

National September 11 Memorial & Museum (Board Member)

New York State Bar Association (Former Board Member)

St. John's Loughlin Society (Benefactors' Council)

St. John's University School of Law Dean's Advisory Counsel

Publications

The Cost of Contamination, American Water Works Association Journal, What's New in Water and Waste Water, November 2012

Compensation through legislation for 9/11 responders and victims: An analysis of Zadroga (Co-Author Brian Crosby), Westlaw Journal - Toxic Torts, Volume 29, Issue 8 / June 2011

Physician Liability In Diet Drug Litigation, Paul J. Napoli NYLJ April 20, 1998

Paul J. Napoli has achieved hundreds of million dollar verdicts and settlements for his clients and has also received many awards from his peers.

He serves as a Board Member of the National September 11 Memorial & Museum and has previously served on the Board of Directors of the New York Trial Lawyers Association, is active in several bar associations, has been interviewed on numerous television shows, in newspaper and magazine articles and is frequently consulted by attorneys around the country on a variety of mass tort, professional malpractice and general liability issues.

Paul lobbied New York State and the U.S. Congress for and was instrumental in obtaining two important pieces of legislation to assist WTC- injured workers. These are an amendment to New York's General Municipal Law §50-I ("JIMMY NOLAN'S LAW") that provided a one-year savings statute for otherwise time-barred first responder claims and the JAMES ZADROGA 9/11 HEALTH AND COMPENSATION ACT OF 2010 ("Zadroga Bill"), which provides for medical monitoring and cash awards for injured first responders and other WTC survivors, local office workers and community members injured by the post-9/11 fallout.

Full bio › **goo.gl/DKsvqz**

Louise R. Caro
Partner

Louise R. Caro is the managing attorney for our Miami, Florida office.

Her practice focuses on plaintiff's mass tort litigation, concentrating on helping people harmed by exposure to hazardous soil, water and air contaminants. Ms. Caro has represented clients harmed by a multitude of environmental pollutants and toxins such as arsenic, lead, and dioxin, in soils and public water supply wells.

Full bio › **goo.gl/sqIjZQ**

Patrick N. Haines
Partner

Patrick N. Haines is managing attorney for the firm's offices in Edwardsville, IL as well as in Austin, TX.

His practice focuses on helping victims of asbestos and other toxic substances obtain compensation for their injuries. Patrick has represented over 1000 victims of mesothelioma from all over the U.S. and has successfully tried cases to verdict in Texas and Louisiana. His trial victories include the first asbestos verdicts ever against Borg Warner Corporation and Exxon Mobil. He has litigated cases involving injuries from vinyl chloride, benzene, carbon disulfide and drugs like Vioxx.

Full bio › **goo.gl/sOebsb**

James Heisman
Partner

James Heisman is the managing attorney for the Delaware office.

He has been litigating complex commercial disputes on a national basis for over twenty years. His experience includes intellectual property litigation, unfair competition claims, trade secret and employee non-compete cases as well as construction and general business litigation. He is a frequent guest lecturer on topics involving patent litigation and construction law.

Full bio › **goo.gl/UxO5RC**

Nicholas R. Farnolo
Partner

Nicholas R. Farnolo leads the Product Liability Department.

He represents a variety of local, national and international clients in mass tort, class action, mechanical product liability, aviation, commercial, and personal injury matters. Mr. Farnolo handles all phases of litigation from intake to settlement or trial.

Full bio › **goo.gl/I7F1Pb**

Christopher R. LoPalo
Partner

Christopher R. LoPalo is an experienced litigator who manages the firm's World Trade Center and Pharmaceutical Departments.

His practice primarily focuses on the litigation of complex mass tort litigations involving products liability, personal injury, medical malpractice, wrongful death, environmental, negligence and class actions all over the country. Mr. Lopalo is an integral player in successfully recovering millions of dollars on behalf of the firm's clients.

Full bio › **goo.gl/UbgnnS**

Shayna E. Sacks
Partner

Shayna E. Sacks focuses her nationwide practice on obtaining the best results for her clients in the areas of mass tort litigation, including pharmaceutical products liability, personal injury, medical device and medical malpractice cases.

She was recently appointed to serve as Plaintiffs' Liaison Counsel in the *In Re Plavix Product Liability and Marketing Litigation* by the Honorable Freda L. Wolfson of the United States District Court, District of New Jersey.

Full bio › **goo.gl/4167yF**

Paul B. Maslo
Partner

Paul Maslo is a Partner in the firm's Class Actions and Commercial Litigation Department.

He is also the Department's Chair and the firm's General Counsel. Mr. Maslo has extensive experience representing plaintiffs and defendants in litigation involving securities fraud, antitrust violations, complex financial products, business torts, contractual disputes, valuation, partnership disputes, business dissolution, shareholder oppression, healthcare, and the sale of art.

Full bio › **goo.gl/TAY2fd**

Jennifer R. Liakos
Partner

Ms. Liakos' practice focuses on mass tort litigation, including pharmaceutical product liability, personal injury, and medical device litigation.

She predominantly concentrates on injuries affecting women and children, antidepressant-induced suicide and cases involving injuries caused by toxic shock syndrome. Ms. Liakos has testified before the U.S. Food and Drug Administration (FDA) advisory board on amending the regulations concerning generic manufacturer liability.

Full bio › **goo.gl/wdbPz3**

Results On Record

Building on the firm's ongoing success, we represent clients in complex litigation, arbitration proceedings and mediations.

$ 30.75 Million Settlement
For a class of over 4500 Oklahoma royalty interest owners against several big oil companies for their unauthorized deduction from royalty payments owed to claimants.

$ 650 Million Settlement
The firm negotiated this settlement to resolve the claims of approximately 4,000 Pradaxa® users who claimed to have been injured by the drug.

$ 17 Million Settlement
This settlement was reached on behalf of four U.S. Military Servicemen who were killed in a UH-60A Blackhawk helicopter crash. The action alleged improper maintenance and servicing of the DynCorp International LLC accident aircraft.

Multi-Million Dollar Settlement
'Fracking' Settlement for over 50 residents of Dimock, PA, in actions against a natural gas companies for contamination of their drinking water supply wells. Featured in the award-winning 2010 documentary Gasland that focuses on the environmental impacts of natural gas drilling operations.

$ 47.5 Million Settlement
For injuries sustained by Rescue and Recovery workers at ground zero from toxic dust recovered from The Port Authority of New York and New Jersey.

"Many of our clients come to us at their most vulnerable. Our representation is a combination of compassion and understanding in addition to the best legal representation we can provide."

Marie Napoli, Partner

$ 100 Million Settlement
This settlement was reached on behalf of the injured women who used the birth control device, NuvaRing®.

$ 24.5 Million Settlement
For injuries sustained by Rescue and Recovery workers at Ground Zero from toxic dust at Fresh Kills landfill.

$ 10 Million Settlement
For over 300 residents of Brooklyn, NY, in their action against several oil companies for personal injury and property damage caused by one of the longest ongoing oil spills in United States history.

"We believe in holding those responsible for our client's suffering accountable and we are ready to take on the fight."

Hunter J. Shkolnik, Partner

$ 816.45 Million Settlement
For injuries sustained by Firefighters, Police Officers and Construction Workers at Ground Zero from toxic dust.

$ 7.8 Million Settlement
Value on behalf of customers whose personal and financial information was compromised due to the company's failure to properly protect this information.

$ 2.5 Million Settlement
Against an investment advisor firm for breach of their fiduciary duties to their clients.

$ 52 Million Settlement
For environmental contamination of municipal water supplies of MTBE by Petroleum Refiners and Retailers.

$ 11 Million Settlement
For a water district serving over 48,000 residents in an action against several industrial entities for contamination.

$ 28 Million Settlement
For injuries sustained by Rescue and Recovery Workers at Ground Zero from Toxic Dust while working on the Barges and Piers.

$ 2 Million Settlement
Our client was exposed to asbestos during his career as an insulator. At the direction of the owners and general contractors, he was brought into direct contact with asbestos-containing products through his work. The firm successfully obtained this settlement on behalf of our client and his family against major oil companies such as ExxonMobile, Shell Oil Co., and Chevron/Union Oil as well as major contractors and products manufacturers.

$ 7 Million Settlement
For a water district and its more than 3,000 clients for damages resulting from MTBE contamination of drinking water supply wells in Rhode Island.

$ 8 Million Federal Court Settlement
The firm obtained this settlement on behalf of a senior citizen who was struck by a Mack truck tractor trailer while walking in a crosswalk. The pedestrian suffered a traumatic leg amputation after being run over by the truck.

$ 950,000 Settlement
This medical malpractice settlement was obtained on behalf of a husband and two young children who lost their wife and mother after her serious streptococcal infection went undiagnosed.

"Effective case management is a key component to success. We strive to provide excellent customer service while working towards justice for our clients."

Paul J. Napoli, Of Counsel

On the air and in the media.

Press Highlights

Napoli Shkolnik PLLC partners and attorneys remain at the forefront of many litigations and therefore are sought after speakers. They have been interviewed in newspaper and magazine articles around the country on a variety of legal issues.

May 1, 2017

Arkansas Execution Sparks Outrage

Fox News

Hunter comments on the 4th Arkansas death-row execution in 8 days.

April 7, 2017

Man Charged with Killing Shoplifter

HLN | PrimeTime Justice

Marie discusses the credibility of the man accused of shooting the fleeing suspect nine times.

April 12, 2017

Call For Investigation into United Airlines

Fox Business | Breaking

Hunter says that United Airlnes is now facing a multi-million-dollar lawsuit.

April 7, 2017

Cops Want to Know Why Teen Allegedly Killed Stepmom

HLN | PrimeTime Justice

Marie offers a possible legal defense for a murder suspect who is in his teens.

April 11, 2016

Former U.S. House Speaker Dennis Hastert Scandal

CBS News | Justice

Hunter is not sure there will ever be justice in this case.

April 7, 2017

Mystery Deepens After Coed Vanishes: Was She Kidnapped?

HLN | PrimeTime Justice

Marie speaks about the possible kidnapping of a young woman.

April 11, 2017

Aaron Hernandez Murder Trial

LawNewz | Live Coverage

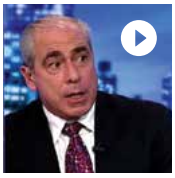
Marie weighs in on Aaron Hernandez's lead attorney's, Jose Baez, closing arguments in the murder trial.

April 6, 2017

Young Woman Burned Alive Murdered?

HLN | PrimeTime Justice

Hunter discusses a woman burned alive in her home as neighbors heard her screams for help.



April 6, 2017

Murder on Video

HLN | PrimeTime Justice

Hunter talks about a mother of 3 young children who is shot to death in front of her kids while driving to daycare.

March 21, 2017

FBI Began Trump Investigation in July 2016

Fox News | Strategy Room

Marie appears on the show to talk about FBI Director Comey's testimony before Congress.

April 4, 2017

Aaron Hernandez Double Murder Trial

LawNewz Network | Live

Hunter talks through the opening statements, witnesses, testimony and sidebars of the Aaron Hernandez murder trial.

March 21, 2017

Neil Gorsuch Faces Tough Hearing

Fox News | Strategy Room

Marie speaks about Neil Gorsuch's Supreme Court Confirmation Hearings.

March 28, 2017

Nash Landfill Suit Filed

Spectrum News

Louise explains the notice of claim that was filed on behalf of residents living near the toxic Wheatfield landfill.

March 20, 2017

Residents Exposed to Contaminated Wells

News12 Long Island

Marie informed viewers about blood testing and on the health risks associated with contaminated well water.

March 23, 2017

Chemical Exposure Lawsuit

WCBS News

Marie discusses the importance of medical monitoring for the Westhampton, Long Island community.

March 13, 2017

Man Convicted of Scalping Girlfriend, Mouths Off to Judge

HLN | PrimeTime Justice

Marie says the defendant's disrespect to the Court might have impacted his sentencing.

March 13, 2017

Ex-Porn Star Testifies About Relationship with MMA Fighter

HLN | PrimeTime Justice

Marie's opinion is that War Machine's ex-girlfriend provoked the attack.

February 8, 2017

Texas Rangers Join Search for MVP's Jersey

HLN | PrimeTime Justice

Hunter speaks about the value of Tom Brady's missing Super Bowl jersey.

March 9, 2016

City of Flint Water Emergency

Local Affiliate | New at 4

Hunter explains how children are facing neurological damage due to lead exposure.

January 29, 2016

Flint Water Crisis Fallout

Fox Business | News Alert

Hunter represents clients in Flint, Michigan.

February 8, 2017

Britney Spears' Niece Injured After Driving Into Pond

HLN | PrimeTime Justice

Hunter discusses Britney Spears' niece's ATV accident.

January 26, 2017

"Catwoman" Facing Felony Charge In Brawl with Ex

HLN | PrimeTime Justice

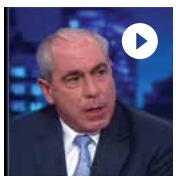
Hunter speaks on divorce, settlements and domestic violence.

February 8, 2017

Armed Customer Shoots, Kills Alleged Shoplifter

HLN | PrimeTime Justice

Hunter comments on whether or not a recent Walmart shooting is felony murder.



January 26, 2017

Home Health Care Horror

HLN | PrimeTime Justice

Hunter speaks on elder abuse incident.

January 26, 2017

Mom Charged with Murder

HLN | PrimeTime Justice

Hunter remarks on a family dispute that resulted in murder and child suicide.

June 7, 2016

Businesses React to NC Law

Fox Business | Cavuto Coast to Coast

Marie talks about the North Carolina transgender bathroom laws.

January 26, 2017

Truck Swerving on Interstate Crashes into Police SUV

HLN | PrimeTime Justice

Hunter expresses his opinion on civil liability, heron use and DWI.

December 29, 2015

Breaking News: Black Lives Matter

Fox Business | Exclusive

Marie speaks on the Mall of America protests.

October 17, 2016

Can Trump Successfully Sue New York Times?

WHDT World News 9

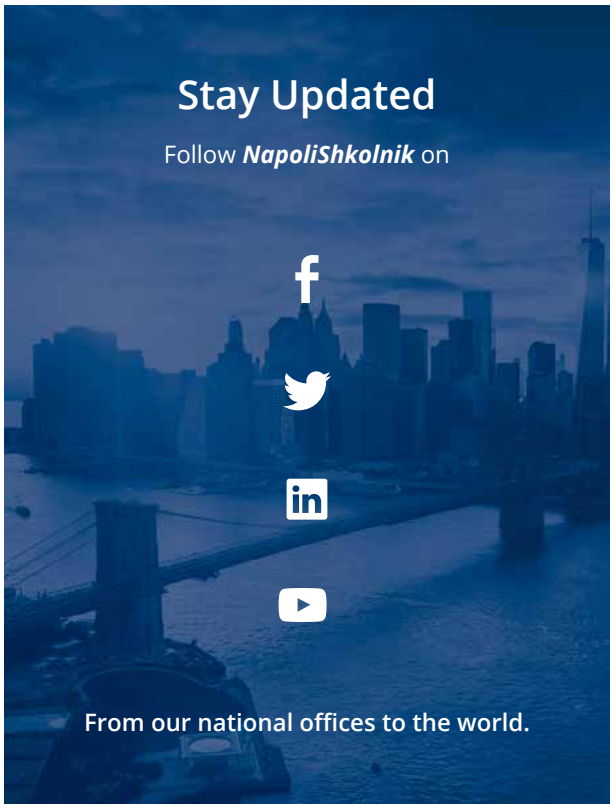
Hunter speaks about Donald Trump's threat to sue the NYT for libel.

August 17, 2016

Michigan Couple Suing Pokemon Go Creators

Fox News | Your World With Cavuto

Hunter questions whether or not this case has merit.



April 20, 2017

Rookie Judges Start to Wrangle MDL Dockets

Amanda Bronstad | The National Law Journal

Lawyers who sued Stryker Orthopaedics over recalled hip implant components wanted a single judge to oversee about 30 cases filed in the past year. At the top of their list was U.S. District Judge Frank Donovan in Minnesota—an obvious choice, having overseen thousands of cases brought over another Stryker hip implant that settled for $1 billion.

But on April 5, the U.S. Judicial Panel on Multidistrict Litigation instead chose U.S. District Judge Indira Talwani in Boston, a relative newcomer to the federal bench who has never before handled a multidistrict litigation proceeding, or MDL.

In its order, the panel noted that five of the Stryker cases were already pending in her courtroom. Further, it said, she had "not yet had an opportunity to preside over an MDL docket."

That's become an increasingly common phrase in orders from the MDL panel, which in 2016 transferred cases to 15 first time MDL judges, according to a review of the panel's assignments conducted by The National Law Journal. It's the first time in at least five years that the majority of judges chosen to oversee an MDL had never done it before.

Among the new initiates to the complex world of MDL litigation are Obama appointees Lorna Schofield in Manhattan Ketanji Brown Jackson in Washington, D.C.; Vince Chhabria in San Francisco; and Brian Martinotti in New Jersey. Notably, as the baton passes to a new generation of MDL judges, more women and minority jurists have been drawn into their ranks.

The widening circle is no fluke, said U.S. District Judge Charles Breyer of the Northern District of California, one of seven federal judges from across the country who comprise the MDL panel.

"Although it is unusual for a newly appointed judge to have experience and understanding of mass torts in general, here we not only have a highly skilled and well qualified jurist, but also one with extensive and successful experience in the highly complex pharmaceutical mass tort field," wrote Hunter Shkolnik, a partner at New York's Napoli Shkolnik.

"There has been an effort to reach out to newer judges, to bring them into the MDL process, so as to give a greater MDL experience to the judiciary as a whole," said Breyer, a veteran MDL judge himself. "You need a skill set in order to handle very large cases, but the only way you acquire that skill set is through experience. We look for MDL judges who are new to take smaller cases, to acquire the skill set, so eventually they'll get to the larger case."

Read further › **goo.gl/Hn8Tts**

April 19, 2017

Napoli Shkolnik to Appear Before The United States Supreme Court

Market Wired

The issue being heard is a challenge to the California Supreme Court's decision that out of state victims may sue in California.

Plaintiffs, including representatives from Napoli Shkolnik, appeared before the United States Supreme Court. The Court is considering a challenge to California's highest court decision which upheld the rule of law that out-of-state victims can join California residents in suing a pharmaceutical company in California State Court where the claims and injuries are similar.

This case involves litigation filed on behalf of hundreds of individuals from 33 states who sustained injuries associated with the drug Plavix®. The Superior Court of San Francisco, the Court of Appeal of the State of California and the Supreme Court of the State of California all validated Plaintiffs' position that corporations must be held accountable for the injuries their products cause. Bristol-Myers Squibb Company challenged these decisions at every turn.

Partner Marie Napoli said "the impact of this decision will have far reaching effects on the rights of victims in their fight against corporate greed and influence."

Since the inception of this litigation, Plaintiffs have successfully argued that contacts with California were sufficiently "related to" the claims of the out-of-state plaintiffs to justify an exercise of specific jurisdiction based in large part on their nationwide marketing and promotion decisions.

Multiple briefs in support of Plaintiffs were filed by various advocacy groups, nonprofit organizations, public interest groups, and educators.

Napoli Shkolnik PLLC is looking forward to presenting Plaintiffs' position to the Justices along with appellate counsel Thomas Goldstein of Goldstein & Russell P.C. Shayna E. Sacks, a partner with the firm, said she is "confident that the United States Supreme Court will agree with the California Supreme Court and continue to hold the pharmaceutical industry and other large corporations responsible for their deceptive nationwide practices."

Read further › **goo.gl/hLhS6A**

April 18, 2017

LaBelle Residents File Federal Lawsuit Over Coal Waste Dump

Scott Beveridge | Observer-Reporter

Residents of a Fayette County village have filed a federal class-action lawsuit against FirstEnergy Corp. and others claiming they are being subjected to dangerous chemicals from fugitive dust that leaves a large coal waste dump along the Monongahela River.

The plaintiffs from LaBelle filed the lawsuit Friday seeking relief in the form of health monitoring from the corporation, as well as NRG Energy Inc. and Matt Canestrale Contraction Inc. of Belle Vernon, the court record indicates.

"I think the people that live there in LaBelle are being completely ignored and have been poisoned for some time, and it's not going to stop," said their attorney, Louise R. Caro of Philadelphia. "That dust is not contained, and with the weather, wind, LaBelle is always getting inundated with this dust."

The lawsuit claims the residents have been subjected to dust from the 506.7-acre site that includes lead, arsenic, cadmium and chromium. The site dates to 1903, when it was owned by Vesta Coal Co., a subsidiary of Jones & Laughlin Steel Corp. It quickly became the largest coal-preparation processing site in the world, the lawsuit states.

The owners of the site went bankrupt in the 1990s before Canestrale entered into a contract in 1995 to purchase the processing company's assets. Canestrale also entered into a consent agreement with the state Department of Environmental Protection in 1997 that outlined its duties to reclaim and close the site, the lawsuit contends.

Canestrale reclaimed the site with coal ash generated at power plants operated by First Energy of Akron, Ohio, and NRG Energy of Princeton, N.J., Caro stated in the lawsuit. "The pile covers a large hill that looms high over the town of LaBelle, Pennsylvania," she stated in the records.

"I think the people that live there in LaBelle are being completely ignored and have been poisoned for some time, and it's not going to stop," said the resident's attorney, Louise R. Caro.

"The coal ash is sent by open, uncovered barge to the prep site and then by open, uncovered truck up to the refuse site."

Caro said such an operation should not have been conducted so close to homes.

FirstEnergy spokeswoman Stephanie Walton said Pennsylvania promotes the use of coal ash to close and reclaim legacy mine property, and that thousands of acres of land have been successfully reclaimed with the material across the state.

"No material from FirstEnergy power plants is currently being beneficially used at LaBelle," Walton said.

She said FirstEnergy is reviewing the lawsuit.

Read further › **goo.gl/BCuJe5**

April 16, 2017

Health Clinic Got Me Hooked On Opioids for Financial Gain: Suit

Julia Marsh | New York Post

When Alvin Floyd arrived at Parkville Medical Health in Brooklyn on April 7, law-enforcement officials were raiding the alleged pill mill.

"I had a panic attack," Floyd, 66, recalled. "I knew I wasn't going to get my medication."

Then the withdrawal started.

"I was throwing up, having stomach cramps and I couldn't hardly sleep. I got depressed. I've been depressed since then," he told The Post.

Floyd has filed the first lawsuit related to the alleged narcotics scheme, which allegedly was perpetrated, in part, by former state Assemblyman Alec Brook-Krasny (D-Brooklyn).

Floyd, of Harlem, first started seeing doctors at Parkville nearly five years ago for relief from pain related to a hip replacement.

He says doctors eventually prescribed him as many as 120 30-milligram pills at a time, and he was popping up to six pills a day, including oxycodone, oxymorphone, morphine, muscle relaxants and other opioids.

"My blood pressure went up and I started gaining weight," Floyd said. "The opioids made me feel like I was in a fog. I just couldn't focus."

He says a clothing line he had started folded and he could no longer pursue his dream of recording music.

The physicians at the Brooklyn clinic, led by Dr. Lazar Feygin, also performed unnecessary tests on patients for reimbursements from Medicare and Medicaid, the suit alleges.

"They (the defendants) acted with complete disregard for human dignity," said Paul Napoli.

The Brooklyn Supreme Court lawsuit seeks unspecified damages against Feygin, Brook-Krasny, the clinic, pharmaceutical companies and Duane Reade, where he filled his prescriptions.

The suit says the companies and the pharmacy ignored obvious red flags that the clinic was operating a pill mill.

"Dr. Feygin and his staff took advantage of their patients to continue to fund his lavish lifestyle, at the expense of the health of patients such as Mr. Floyd," said his attorney Joseph L. Ciaccio, of the law firm Napoli Shkolnik.

"They acted with complete disregard for human dignity," said Paul Napoli, another attorney for Floyd.

Brook-Krasny, who resigned from the Assembly in 2015, was one of 13 people indicted April 7 for allegedly helping facilitate a multimillion-dollar pill-mill ring in Brooklyn.

Reps for Feygin and Brook-Krasny did not return messages. A Duane Reade spokesman declined to comment on the pending litigation.

Read further › **goo.gl/hJnbbo**

April 7, 2017

Law Firm Advertises Hyannis Water Class-Action Suit

Geoff Spillane | Cape Cod Times

Lawsuit would be latest in growing web of legal action based on contamination from firefighting foams.

Manhattan-based law firm is seeking clients who believe they may have been poisoned by contamination of the Hyannis water supply.

Napoli Shkolnik, PLLC began running advertisements on Facebook this week in connection with the planned class action. In addition, letters to residents and businesses in the Hyannis Water District are being mailed, according to Louise Caro, a partner in the firm who specializes in litigation involving exposure to hazardous soil, water and air contaminants.

The firm has created a website for the potential action: massachusettswater.napolilaw.com.

"It is not uncommon for these so-called mass tort law firms to reach out with public announcements to identify potential clients," Barnstable Assistant Attorney Charles McLaughlin said.

Barnstable town officials have issued public health advisories for the Hyannis water system twice since 2015. In both instances, levels of the perfluorinated chemicals PFOS and PFOA above the U.S. Environmental Protection Agency health advisory limits were found in wells serving 18,000 residents and businesses in Hyannis, Hyannisport and West Hyannisport.

The chemicals are typically found in the types of firefighting foams that have been used in the past at the Barnstable County Fire and Rescue Training Academy and Barnstable Municipal Airport.

"We are looking back a long time for exposure," Caro said. "We suspect it was significant.

The temporary advisories warned pregnant women, nursing mothers and infants to avoid consuming water from the public water supply. Carbon treatment systems have since been installed and the water is again safe to drink, according to town officials.

Perfluorinated chemicals have been linked to health problems that include thyroid disorders, developmental effects on fetuses during pregnancy, liver damage and testicular and kidney cancer.

"Residents of Hyannis have been unknowingly poisoned by the town water for years. It is time that those responsible for making and releasing those contaminants into our water system clean it up and help those people who developed cancers," read a Napoli Shkolnik Facebook ad that appeared online on Wednesday. "Did you drink the water? Get started filing your claim today!"

Caro said she expects the filing of a class-action lawsuit, which has already been drafted, to occur quickly.

"Once we start receiving responses, we will go to Hyannis and have a town hall style meeting with a toxicologist attending by Skype," she said. "This can happen very fast, in just a couple of weeks."

Read further › **goo.gl/uUFZU8**

March 27, 2017

Lawsuit Filed Against Town Over Possible Soil Contamination

Callan Gray | News 4 Local Affiliate WVIB

Legal action against the Town of Wheatfield is moving forward.

Some Niagara County residents say they're sick from contamination from Love Canal waste disposed of at the Niagara Sanitation Landfill.

The DEC finished remediation of the Love Canal waste at the landfill last year and plans to do more testing this spring.

A complaint has now been filed on behalf of at least 60 people who live near the landfill.

The Napoli Shkolnik PLLC, Smith Stag L.L.C., and lawyer Christen Civiletto are representing the residents.

Louise Caro, the head of the environmental law department for Napoli Shkolnik, told News 4 summons will go out on Monday to the Town of Wheatfield, Niagara Sanitation Company, Occidental Chemical Corporation, Bell Helicopter Textron Inc., Saint-Gobain Abrasives, Roe Consolidated Holdings, Graphite Specialties, Crown Beverage Packaging, and Grief Inc.

Since January, more than 160 notices of claim have been filed. Caro told News 4 the Town of Wheatfield has 30 days to respond to those notices of claim but that time has run out for some of those notices.

This complaint represents only some of the notices of claim, Caro said there will be more lawsuits filed.

The complaint filed on March 26 seeks monetary damages for personal injury, monetary damages for property damage, and calls for medical monitoring.

"We continue to do testing and we're finding more contamination," said Caro. "We're finding contamination in people's homes that are unlivable.

Medical monitoring would require a fund be set up to have doctors test residents to see what they have been exposed to.

"A lot of people are sick, it's amazing how many people are sick actually," said Caro.

The complaint alleges not enough action was taken to prevent residents from exposure to toxic chemicals. The three law firms have been conducting soil tests and the complaint outlines each of the toxins they say they discovered.

"We continue to do testing and we're finding more contamination," said Caro. "We're finding contamination in people's homes that are unlivable."

She said environmental cases can take years to resolve.

"Here I think we need some movement and action sooner than normal because it's that critical," said Caro.

She told News 4 they expect more affected neighbors to come forward.

Read further › **goo.gl/b7p9s6**

March 27, 2017

Newburgh Hauled Into Court Over Toxic Water

Christine Stuart | Courthouse News Service

Unaware before this summer that they have been bathing in, drinking and cooking with toxic water, dozens of Newburgh, New York, residents are fighting to file a late notice of claim.

The March 22 petition in Orange County Supreme Court comes seven months after state regulators bestowed ignominious Superfund status to the Stewart Air National Guard Base, just 2.5 miles west of Newburgh.

Overseen by the federal government, the Superfund program is designed to clean up sites of toxic waste. Lead plaintiffs Desiree and Robert Sampson say the base's designation means that there have been "alarming levels" of the toxic chemical perfluorooctanesulfonic acid, otherwise known as PFOS, in Newburgh's public and private supply wells since at least 2014.

Joined by 31 other current and former Newburgh residents, the Sampsons say Newburgh's negligence exposed them to PFOS and PFOA, short for perfluorooctanoic acid, causing "severe and permanent personal, physical, emotional, and psychological injuries."

Seeking leave for having exceeded a 90-day time limit to file claims, the residents note has nevertheless been aware of the facts underlying their claims within the 90-day period.

"In fact, the city of Newburgh was aware of the PFOS in the drinking water before any of its customers and will be in no way prejudiced by the four-month delay in filing the notice of claims," the petition states.

There has been no prejudice either, the residents say, since their health statuses have not changed, and the

In fact, the city of Newburgh was aware of the PFOS in the drinking water before any of its customers...

contamination investigation remains ongoing, with officials taking citizen blood samples "to this very day."

The residents are represented by Tate Kunkle of the Manhattan firm Napoli Shkolnik.

Attorneys for the city have not returned a request for comment.

Newburgh, pop. 28,000, is about 90 minutes north of New York City.

PFOS was detected in Lake Washington, the city's drinking water supply, three years ago at a level of 170 parts per trillion, which at the time was below the recommended 400 parts per trillion recommended by the U.S. Environmental Protection Agency. The EPA later set a new level of 70 parts per trillion, and Newburgh declared an emergency in May 2016, shifting to a new water source.

Officials have accused Stewart Air National Guard Base of using the chemical PFOS for years at in firefighting emergencies and drills.

Read further › **goo.gl/n74CAs**

February 23, 2017

Homeowners Near Westhampton Air Base Plan To Sue Suffolk County Over Drinking Water Contamination

Erin McKinley | The Southampton Press

Isaac and Arneal Green said they've heard rumblings about possible drinking water well contamination for years.

That is the main reason why the couple, who live on Hazelwood Avenue in Westhampton Beach, have had their private water well tested for contaminants every few years since moving to the area in 1976.

Those tests have always come back negative—which made it all the more surprising when they were contacted in July by Suffolk County officials who wanted to test their well water for two new chemicals, perfluorooctane sulfonate, or PFOS, and perfluorooctanoic acid, or PFOA.

It turns out that those chemicals, since traced back to fire suppression foam used in the past at the New York Air National Guard base at Francis S. Gabreski Airport in Westhampton, were never included in testing, because they were never deemed a hazard by the federal government.

That has since changed, and, within two days of being contacted by the county, the Greens learned that their well had tested positive. A second round of testing revealed that their water contained elevated levels of one of the contaminants specifically, their water contained 0.086 parts per billion of PFOA, above the Environmental Protection Agency's new recommended safe level of 0.07 ppb.

They were immediately instructed to stop drinking their well water, and the county began sending them weekly water bottle deliveries. In December, the Suffolk County Water Authority finished hooking up their home to public water at no cost.

"Almost every household in the area has some serious illness," Napoli Shkolnik PLLC client Ms. Liggon said. "Not one individual house that doesn't have a health ailment that needs to be monitored."

"I had heard inklings of possible contamination at the base years ago," Mr. Green said this week. "But it was never really mentioned what it was and then, all of a sudden, it became a thing. I don't know who put a flame under whose rear-end, but it became a big thing—fast."

The Greens are now listed as plaintiffs in a notice of claim filed on October 20 against Suffolk County, which owns the airport where the chemicals have been traced. The notice, typically a precursor to an actual lawsuit, contends that the county was negligent in protecting homeowners with private wells for decades. In total 39 notices have been filed against Suffolk County, representing more than 100 residents from Westhampton, Westhampton Beach and Quiogue.

Read further › **goo.gl/nELt9X**

February 8, 2017

Napoli Shkolnik PLLC Files Lawsuit Against Helicopter Manufacturer

Military & Aerospace Electronica

Napoli Shkolnik PLLC, on behalf of its clients, filed suit against AgustaWestland Philadelphia Corp. in the United States District Court for the Southern District of California. AgustaWestland is the North American distributor of Agusta A1091A and A109A MK II helicopters.

These helicopters were identified last year by the FAA as being defective. As the Complaint notes, "[b]ecause of the tiny interior cracks that may develop with the Aircraft's blades, the FAA requires owners to engage in a four-hour inspection process prior to using the Aircraft. This effectively renders the Aircraft unusable. Nor is the defect remedied by blade replacement because all available replacement blades would suffer from a similar defect and require the same onerous inspection process after 500 hours of use."

According to the Complaint, Agusta Westland deceived purchasers by knowingly failing to disclose this defect when the helicopters were first sold and, even after the FAA's warning...

According to the Complaint, AgustaWestland deceived purchasers by knowingly failing to disclose this defect when the helicopters were first sold and, even after the FAA's warning, failed to do anything to compensate owners in any way.

The complaint alleges claims under California consumer fraud and warranty laws, as well as common law fraud claims. Napoli Shkolnik will be filing additional lawsuits on behalf of owners in other states.

Napoli Shkolnik PLLC is experienced in the field of consumer litigation. The firm has achieved billions of dollars in recovery for their clients, including in the field of aviation-related litigation. The firm believes that the owners of these aircraft should receive compensation.

October 5, 2016

Lawyers Want Affected, Blood Tested in Water Contamination Lawsuit

Ted Skroback | KOAA 5
(NBC Affiliate Colorado)

The class action lawsuit being filed over groundwater contamination in the Fountain/Security/Widefield area is going after manufacturers of the fire retardant used by the air force that seeped into the ground water supply leaving behind accelerated levels of cancer causing PFC's.

McDivitt Law is teaming up with a law firm from New York that specializes in environmental class action awsuits. They are in town meeting with clients of the lawsuit against

manufacturing companies who they say should pay victims for high amounts of PFC's found in the Fountain/Security/Widfield water supply.

"I said we need to have some heavy hitters to help us out, this is a, this is a big case because there's a lot of people involved and the people on the other side we feel should be held accountable have more money than God, "said Mike McDivitt.

There are six manufacturing companies named in the lawsuit, but no mention or intention of going after the Air Force that used the foam as a fire retardant.

"They've produced no documents to show that they've notified the end user of the appropriate way to use this," said Paul Napoli of Napoli Shkolnik PLLC from New York, "so to be careful that if you put it on the ground it's somehow going to end up in the water."

The law offices also think the government should pay to get residents in affected area blood tested, they say up to 70,000 thousand people could be affected.

"These companies have the obligation if they're going to sell the product to warn appropriately, let every end user know how to use it safely and whether or not you can affect the surrounding environment," said Hunter Shkolnik.

"If you get a blood test for $700, if you multiply that times everybody that needs to be blood tested that's a very expensive proposition. We think it's a community health problem, we think it's a public health problem," said McDivitt.

The lawsuit started with over 1,000 signatures and is now over 1,500.

"These companies have the obligation if they're going to sell the product to warn appropriately, let every end user know how to use it safely and whether or not you can affect the surrounding environment," said Hunter Shkolnik.

There's a second class action suit field a Denver law firm, a court could find that it's best the two lawsuits merge.

Read further › goo.gl/qMN0SV

October 1, 2016

Flight Attendants Sue Boeing Over Sudden Descent Injuries

John Marzulli | Daily News

The Boeing aircraft company is being sued by seven flight attendants who were injured when their American Airlines jet plunged 4,000-feet nose-first in less than one minute due to a freak incident in the cockpit.

The suit alleges that as the first officer sat down, his allegedly defective flight seat lurched to the full-forward position trapping him against the plane's yoke, and disengaging the auto-pilot.

The Boeing 777 dipped out of control, experiencing a "sudden, dangerous, and panic-inducing instantaneous negative G descent," according to the suit filed in Brooklyn Federal Court.

The near catastrophe occurred as the jet approached Ezeiza International Airport in Argentina on Oct. 3, 2014.

...The flight attendants were still up and about securing the serving carts, said lawyer Hunter Shkolnik. The flight crew was tossed like rag dolls, and some suffered broken bones.

About 300 passengers on the flight from Kennedy Airport to Buenos Aires were strapped in their seats, but the flight attendants were still up and about securing the serving carts, said lawyer Hunter Shkolnik.

The flight crew was tossed like rag dolls, and some suffered broken bones. All are dealing post-traumatic stress disorder as a result of the near-death experience, the suit says.

Two spouses of the plaintiffs are also suing Boeing and Ipeco, the maker of the flight seat.

The pilots were able to bring the huge jet under control and make a safe landing.

A spokesman for Boeing which makes the aircraft, declined comment. Messages sent to Ipeco and American Airlines representatives were not returned.

Read further › goo.gl/sN5XV8

September 16, 2016

Northrop Grumman Hit With $500M Chemical Exposure Suit

Adam Lidgett | Law360

(Editing by Patricia K. Cole)

A group of Long Island residents have filed a $500 million proposed class action in New York state supreme court against Northrop Grumman, alleging the defense contractor exposed the residents to toxic chemicals that came from its manufacturing operations.

The 15 Bethpage, New York, residents said that for nearly six decades, the company generated and disposed of toxic contaminants and byproducts from the airplane, weapons and satellite manufacturing operations at its facilities and other landfills as part of routine business, resulting in extensive pollution in the area. The proposed class said the company didn't fairly warn them of the alleged contamination in the more than 600acre area.

"The defendants intentionally and/or negligently failed to adequately warn or advise plaintiffs and the class and other members of the public as to the nature, extent, composition, effects and location of the contamination, the fact that plaintiffs and the class and their property were being exposed to the contamination, the nature of the contaminants and risks could change over time and that exposure to the contamination could likely cause life-threatening and permanent adverse health effects," the proposed class said in its complaint filed Tuesday.

While manufacturing airplanes and weapons for the U.S. Department of Defense, Northrop

Grumman disposed of certain cancer causing chemicals such as arsenic, cadmium, lead, mercury, polychlorinated biphenyls and volatile organic compounds that led to extensive pollution, the proposed class said.

Since 2005, there has been an ongoing investigation of a contamination plume emanating from a community park in the area that was once owned by the company, the proposed class alleged.

Louise Caro, head of the environmental department at Napoli Shkolnik PLLC, the firm that filed the suit, said time is of the essence. "The company has a history of taking a very long time to get things resolved," Caro said. "The people really needed to get some relief from the courts here."

The residents said the plumes contaminants have migrated to their properties and have led to serious health concerns and personal property damage. The suit said the residents have been exposed to the chemicals in water, air and soil. Some of the residents of the proposed class have developed certain diseases, including breast cancer and non-Hodgkin lymphoma, the complaint said.

The proposed class is asking for personal injury and property damage claims and for a medical monitoring program to research the effects of the exposure to the toxic chemicals alleged in the suit and to monitor the health of people in the area, according to the suit.

Read further › **goo.gl/Gy5Zr8**

September 8, 2016

A False Conviction Is Overturned, But the System That Allowed It Remains

Jim Dwyer | The New York Times

Here is the case of a missing paragraph that turned into a trap door that dropped a man into prison.

The paragraph vanished from a police report in a Brooklyn criminal case, but essential information has been hidden from people accused of crimes in courthouses across the country. Even though failing to share exculpatory information is among the most serious breaches of ethics and law for the police and prosecutors, there is little personal or institutional accountability for such tactics.

In 2010, to convict a man named Wayne Martin of killing two people during a stickup of a Brooklyn tire repair shop, someone in law enforcement went to the trouble of blanking out a paragraph in a homicide report.

The erased portion said that a witness had identified someone other than Mr. Martin as the gunman.

In still another report, another witness also told detectives that it was not Mr. Martin who had done the shooting.

Neither of these two reports made it into the hands of Mr. Martin or his defense lawyers before he was tried. Convicted of the double homicide, he was sentenced to life without parole.

On Wednesday, Ken Thompson, the Brooklyn district attorney, moved to dismiss all charges against Mr. Martin, as The Daily News reported. Prodded by Mr. Martin's own legal filings from prison, and by his lawyer, James D. Henning, the district attorney's office had dug into the case files and found the two documents.

Anyone who followed the fictional HBO series "The Night Of" saw a prosecutor in a murder trial deciding not to let a defense lawyer know that a new suspect had emerged.

In a week alone, Mr. Martin's case was one of at least two to appear in New York City courts that had been built on withholding exculpatory evidence.

In a 1963 ruling, the United States Supreme Court said that people being tried on criminal charges had an absolute right to that information. That case, Brady v. Maryland, held that information "material" to questions of guilt or punishment must be shared with the defense, a standard that was not as straightforward as it seemed.

"The materiality test that Brady sets up is poorly designed," said James B. Doyle, a lawyer who has written frequently on miscarriages of justice and what he sees as a misplaced focus on blaming a single person or cause for them.

The Brady test relies on individual prosecutors to make a decision — out of sight of anyone else — about whether a piece of information is "material" to the trial. This is like asking baseball pitchers to call balls and strikes, or tennis players to decide if their own serves were in. Mr. Doyle said that prosecutors may have honorable intentions that are eroded by subtle pressures to win trials, excessive fear of losing them or zeal to cinch cases against defendants they are convinced are bad.

Read further › **goo.gl/q61IOB**

July 6, 2016

Napoli Shkolnik PLLC Files Class Action Against Quest Diagnostics and ExamOne

Benzinga

Napoli Shkolnik PLLC filed a class

action lawsuit in the Southern District of New York on behalf of lead plaintiff and New York County resident, Maria Vecchio, and on behalf of all others similarly situated, against Quest Diagnostics Inc., ExamOne World Wide Inc., and ExamOne LLC.

Our firm is also seeking to represent other current and former Mobile Examiners who worked for Quest and affiliated Quest entities across the country. Our lawsuit alleges the following violations:

- Not paying overtime wages;
- Not paying New York and federal minimum wage;
- Not providing employees proper wage statements (pay stubs); and
- Not reimbursing business expenses.

The plaintiff is possibly one of thousands of New York and national employees who work or worked for Quest as Mobile Examiners and were not paid in accordance with federal and state law.

Ms. Vecchio and her attorneys believe that Quest and its subsidiaries have violated the above state and federal labor laws. She is possibly one of thousands of New York and national employees who work or worked for Quest as Mobile Examiners and were not paid in accordance with federal and state law. This action is presented as an opt-in collective action on behalf of herself and all similarly affected individuals for violations of the federal Fair Labor Standards Act, as well as a class action for Quest's violations of state labor law.

Mobile Examiners who worked for Quest within the past 6 years, and you believe their rights were violated as described above or in any other way, are encouraged to contact an NS attorney today.

June 22, 2016

My Kid Got Sunburned Because of Mislabeled Sunscreen

Ross Toback | New York Post

Additional reporting by Jody Godoy and Joe Van Acker. Editing by Ben Guilfoy.

Jumping on a report that found many sunscreens overstate their protection factors, a Brooklyn parent has filed a class-action lawsuit against the makers of Banana Boat Sunscreen, saying he bought a bottle of kids lotion that was supposed to be SPF 50 but turned out to only have an SPF of 12.

"Defendants have known, or should have known, for years that Banana Boat Kids SPF 50 products contain less UV protection than Defendants advertise," reads the lawsuit, which was filed Wednesday against Playtex Products, Edgewell Personal Care Company and Sun Pharmaceutical.

Paul Lambrakis purchased the tube of Banana Boat Kids SPF 50 in May after a Consumer Reports study found that it and many other sunscreens were overstating their protection factor. He sent the tube to a laboratory in Winston Salem, N.C., to have tested, according to the lawsuit filed in Brooklyn federal court.

The results found that the bottle had an actual SPF that wasn't even half as strong as advertised, court papers say.

"The investigation concluded that Banana Boat Kids SPF 50 sunscreen, clearly labeled as containing SPF 50, shockingly contained only an SPF of 12.69 and a measured UVA protection factor of 4.88," the lawsuit reads.

Now Lambrakis is alleging that he and others in the class action suit were forced to "overpay for the sunscreen based upon false, inflated SPF," according to the documents.

"They were unhappy when the suntan lotion was a complete lie," Lambrakis's lawyer, Hunter Shkolnik, said.

"They were putting this stuff on their children. They made a point to buy it. They were getting burnt."

Hunter Shkolnik accuses the company, which rakes in $25 million in sales each year of "defrauding unsuspecting customers."

He accused the company, which rakes in $25 million in sales each year, of "defrauding" unsuspecting customers.

"You don't want to think its wrong but there's no quality control," he said. "This is a straight-forward case. People are spending money for this stuff!"

Playtex, Edgewell and Sun Pharmaceutical did not immediately respond to requests for comment.

The lawsuit comes after a Consumer Reports investigation found that 43 percent of the more than 60 sunscreens they tested failed to measure up to the SPF claims advertised on their bottles.

"In May of 2016, Consumer Reports research revealed that among 'the most problematic products were Banana Boat Kids Tear-Free, Sting-Free Lotion...which [was] labeled as SPF 50 but [was] found to have only SPF 8,'" the lawsuit reads.

"Defendants have been notified of the false advertisement but have not remedied the problem."

Read further › goo.gl/m73fPc

May 6, 2016

More Uber Drivers Object to $100M Settlement

Matthew Bultman | Law360

Additional reporting by Linda Chiem and Kerry Benn, Editing by Stephen Berg

The list of objections to Uber

Technologies Inc.'s $100 million settlement of a pair of high profile driver class actions continues to grow in California federal court as more people speak out against the deal, including two drivers who on Thursday called the payout "insultingly low."

Leticia Alcala and Marc Borgen said that the settlement, which would end a legal battle over claims that Uber misclassified drivers as independent contractors and denied them proper tips, has caused an uproar due to its unfairness.

Under the deal, which was announced in late April, Uber would pay 385,000 California and Massachusetts drivers $84 million, with an additional $16 million to come if the company goes public and meets certain performance metrics.

Alcala and Borgen, who called it a "sweetheart deal" between Uber and lawyers for the class of drivers, said that based on information provided by the plaintiffs, more than half the settlement class could receive an average of $24 or less.

"Only plaintiffs' counsel and the class representatives — who could receive upward of $73,000 — stand to make any real money in this deal," the two wrote.

How much of the settlement each driver receives will be based on the number of miles he or she has driven during the relevant time period. The deal, which still needs to be approved by a federal judge, also includes several nonmonetary provisions, such as Uber agreeing to provide drivers with more information about their individual ratings and introducing a policy that explains the circumstances under which they could be deactivated from the service.

"Uber has a long, long road to travel before it is in compliance with the labor laws," Paul J. Napoli of Napoli Shkolnik PLLC, told Law360 on Friday. "Technology cannot erase an employer's obligations to maintain a workers basic rights."

The settlement notably does not resolve the central issue in the litigation of whether Uber drivers should be classified as employees rather than independent contractors.

Alcala and Borgen called those nonmonetary provisions "mere window dressing for an otherwise deficient agreement," noting that they are set to expire within two years. Ubermay, however, choose to keep them in place after that.

"Since its announcement, the proposed settlement has received a negative reaction from Uber drivers and the press," they wrote, citing as evidence a poll on Uberpeople.net, a forum for Uber drivers, in which more than 53 percent of the drivers polled felt the settlement was a "setback."

Read further › **goo.gl/HlAqcy**

March 31, 2016

Trio of Plaintiffs' Firms Picked to Lead Daily Fantasy MDL

Pete Brush | Law360

Editing by Catherine Sum

The Boston federal judge handling some 86 suits including class actions accusing daily fantasy sports giants DraftKings and FanDuel of fraud and other illegal conduct picked attorneys from Jones Ward PLC, Napoli Shkolnik PLLC and Stull Stull & Brody on Thursday as co-lead counsel tasked with coordinating a slew of pretrial matters.

The task falls to Jasper D. Ward of Jones Ward PLC, Hunter J. Shkolnik of Napoli Shkolnik PLLC and Melissa R. Emert of Stull Stull & Brody, according to an order from U.S. District Judge George A. O'Toole Jr., who picked up the multidistrict case Feb. 4.

"This slate of attorneys also appears to have broad support among the plaintiffs' attorneys as a whole, further supporting a conclusion that they will fairly and adequately represent the interests of any plaintiff class," the judge wrote.

The group will handle matters including discovery on a wide range of cases with differing theories of liability.

There are "insider trading" cases claiming the companies allowed their employees to gain an unfair advantage in competitors' fantasy contests by using inside information, illegal gambling" cases accusing the companies of violating various antigambling laws and "bonus fraud" cases over an allegedly misleading promotional program used by DraftKings.

A competing motion to appoint John Roddy of Bailey & Glasser LLP, Brendan Glackin of Lieff Cabraser Heimann & Bernstein LLP and Amy Williams Derry of Keller Rohrback LLP as co-lead counsel was denied.

The co-leads said they were honored to have been appointed.

"This slate of attorneys (including Hunter J. Shkolnik) also appears to have broad support among the plaintiffs' attorneys as a whole, further supporting a conclusion that they will fairly and adequately represent the interests of any plaintiff class," the judge wrote.

"We have a very committed group who are dedicated to pursuing this case," Emert said.

Christopher Weld Jr. of Todd & Weld was selected as liaison counsel. An executive committee, to be chaired by the three co-leads, will be comprised of attorneys John A. Yanchunis of Morgan & Morgan, Jennifer L. Duffy, D. Todd Mathews of Gori Julian & Associates PC, W. Lewis Garrison Jr. of Heninger Garrison & Davis LLC, Kevin S. Hannon, Robert K. Shelquist of Lockridge Grindal Nauen & Holstein, Michael J. Flannery of Cuneo Gilbert & LaDuca LLP, Alan Carl Milstein of Sherman Silverstein Kohl Rose & Podolsky, and Richard S. Cornfeld, according to Judge O'Toole.

Two other applications, one filed by Guy M. Burns of Johnson Pope Bokor Ruppel & Burns LLP and one filed by Frank L. Watson III of Watson Burns PLLC, were also denied. Burns had sought a co-lead spot or a spot on an attorney executive committee, and Watson had sought a spot on the executive committee.

Read further › **goo.gl/mZvJDT**

March 16, 2016

Lawyers for Flint Water Victims Hire D.C. Lobbyists

Catherine Ho | The Washington Post

A personal injury law firm representing Flint residents has hired Washington lobbyists to push Congress to create a victim compensation fund for people affected by the Michigan city's contaminated drinking water.

Attorneys at the law firm Napoli Shkolnik previously secured millions of dollars in settlements for firefighters, police officers and other Ground Zero workers for ailments related to the 9/11 terrorist attacks.

This month Napoli hired lobbyists at the boutique D.C. firm Envision Strategy as it pushes to get similar type of relief for the 1,000 Flint residents it represents who are dealing with health issues caused by the city's poisoned water supply.

If approved by Congress, the fund could draw from federal and state money to pay for residents' health care costs.

"The game plan is to try and figure out what the needs are of the people of Flint," said Brett Heimov, a lobbyist at Envision and a former aide to Rep. Jerrold Nadler (D-N.Y.) who previously lobbied for legislation authorizing the 9/11 Victim Compensation Fund. "We'll sit down and reach out to the Michigan delegation to craft legislation to try to make it happen."

The other lobbyists working on the Flint matter are Steve Schultz, Carol Pineau and Steve Stallmer.

The public health crisis in Flint occurred after the city switched to a new water source, the Flint River, in 2014 as a moneysaving measure. But local officials failed to treat the water with a chemical that would have prevented lead in the pipes from corroding and contaminating the water. As a result, thousands of residents were exposed to dangerous levels of lead. For months, residents complained about the taste, odor and color of the water. But officials repeatedly downplayed the concerns.

...The fund could draw from federal and state money to pay for residents' health care costs.

At a House hearing Tuesday, lawmakers criticized former Michigan officials and a former Environmental Protection Agency regional administrator for their roles in the decisions that led to the water contamination in Flint and how they deal with its aftermath.

"You screwed up and you ruined people's lives," House Oversight and Government Reform Chairman Jason Chaffetz (R-Utah) told former EPA official Susan Hedman, who resigned in February in the wake of the crisis.

Michigan Gov. Rick Snyder, who is under pressure to resign, is scheduled to appear before the committee Thursday.

Last month, a bipartisan group of senators led by Michigan Democrats Debbie Stabenow and Gary Peters and Environment and Public Works Committee Chairman James M. Inhofe (R-Okla.), reached a deal to provide funding to help Flint and other cities struggling to replace aging pipes. The deal includes $70 million in credit subsidies for water infrastructure projects, $100 million in subsidized loans for water infrastructure improvements and $50 million for public health programs. The aid package would be offset by rescinding $250 million in loan credits for a program that was intended to help auto companies develop fuel economy technology.

February 18, 2016

Helicopter Crash Lawsuit Revived Against Soffer

Celia Ampel | Daily Business Review

A state appellate court on Wednesday revived a lawsuit accusing billionaire developer Jeffrey Soffer of causing a fatal helicopter crash.

The Third District Court of Appeal will allow Daria Gogoleva, whose attorney-husband died in the crash, to amend her complaint against Soffer and others on the other helicopter. The court reversed Miami-Dade Circuit Judge Daryl Trawick's dismissal of wrongful death, conspiracy and fraud claims.

Soffer led the $1 billion expansion of the Fontainebleau Miami Beach, and his family developed much of Aventura.

"We are thrilled that the appellate court thoughtfully and carefully reviewed all of the arguments, ruled in our favor and provided our clients with the ability to have their day in court," said Gary Phillips of Phillips, Cantor, Shalek, Rubin & Pfister in Hollywood, who represented Gogoleva with his colleague Edward Pfister.

The helicopter carrying Gogoleva's husband, tax attorney Lance Valdez, crashed on Thanksgiving Day 2012 in the Bahamas. Gogoleva's complaint alleges Soffer, who was in the co-pilot's seat, was controlling the helicopter when it crashed. He is a licensed pilot but was not licensed to fly the Aerospatiale Twin Star helicopter.

Pilot David Pearce flew for "at least part of the flight" until it approached the landing site and crashed, killing Valdez and injuring Soffer, Pearce and passengers Paula and Daniel Riordan, according to the decision. Daniel Riordan is an executive with Turnberry Associates, the Soffer family's real estate company.

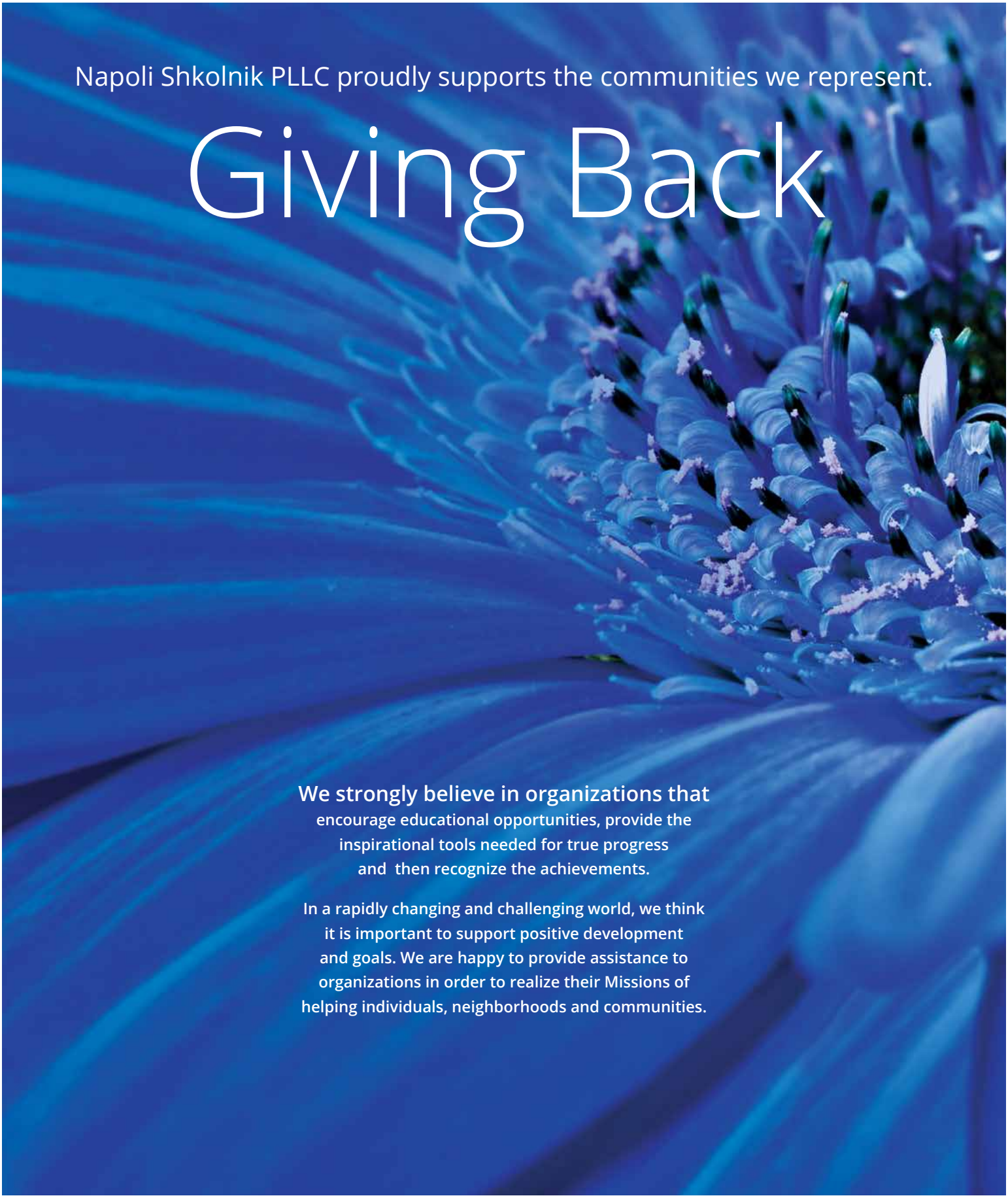
The helicopter was covered by a $2 million North American Elite Insurance Co. insurance policy, and the survivors agreed Gogoleva and her three children should collect the full amount. Her signed release contained an "unusual feature," the Third DCA noted. It included a promise that Gogoleva, Soffer and the Riordans would release each other from future legal claims. All four of them were represented by the same lawyer, Steve Marks of Podhurst Orseck in Miami.

Hunter Shkolnik represents Gogoleva in the federal case and said his client was pleased the Third DCA ruled in her favor. "Now a jury can consider their claim that she was not advised that Mr. Soffer was the pilot when her husband died," he said.

Marks didn't tell Gogoleva there could be a conflict of interest or let her know she wasn't required to release Soffer and the Riordans to receive the $2 million, she claims. Marks is not a party to the lawsuit.

Gogoleva sued Soffer, the Riordans and Alex Krys, a senior executive with Soffer's real estate group who allegedly told Gogoleva she should join the crash survivors in retaining Marks.

Read further › goo.gl/WwYAh1


Napoli Shkolnik PLLC proudly supports the communities we represent.
Giving Back
We strongly believe in organizations that
encourage educational opportunities, provide the inspirational tools needed for true progress and then recognize the achievements.
In a rapidly changing and challenging world, we think it is important to support positive development and goals. We are happy to provide assistance to organizations in order to realize their Missions of helping individuals, neighborhoods and communities.

9/11 Memorial 5K Run/Walk

The firm is always proud to be a Mile Marker sponsor! Our firm teams participate as runners and walkers at the event and locally in their hometowns.

New York City Police Museum

The partners are actively committed to helping the Museum realize its Mission to preserve he history of the New York City Police Department through educational programming and exhibitions.

Nassau County Law Enforcement Exploring Program

This youth program emphasizes Career Opportunities, Life Skills, Citizenship, Character Education and Leadership Experience. It is rewarding to see participants blossom with these characteristics.

The Police Athletic League (NYC)

We are proud supporters of this not-for-profit organization's belief that "young people's individual strengths and capabilities can guide them to mature, productive adulthood" with encouragement and commitment.

National September 11 Memorial and Museum

A historical institution honoring the victims and examining 9/11 and its continued global significance. As a Board Member, Paul is very involved in realizing the organization's message of volunteerism, education and remembrance.

New York City Pancreatic Cancer Research Walk

By supporting this event, Napoli Shkolnik helps to advance the scientific and medical research related to the diagnosis, treatment and cure of pancreatic cancer.

Bone Marrow Foundation

The BMF helps families improve their odds of finding a donor and receive the necessary support as their loved one receives treatment. When Paul Napoli was diagnosed with leukemia and was told he need a life-saving bone marrow transplant, the BMF provided information and support.

New York City Marathon

In honor of Paul's fight against leukemia and to support the families of other patients, Marie collected over $50,000 in pledges to support the foundation's programming by completing the 2015 NYC Marathon.

Swing for a Cure

This charity golf outing benefits the Breast Cancer Research Foundation and in keeping with tradition, Napoli Shkolnik has sponsored a Tee for the event.

Mental Health Association of Nassau County

We are glad that we can make a difference with the MHA, which is a not-for-profit membership organization dedicated to improving mental health in the community through advocacy, education, program development.

St. John's University President's Dinner

The firm is proud to be an annual Sponsor of the Annual President's dinner; an event committed to raising scholarship money in order to provide financial assistance to deserving students.

"Being part of the process of helping to turn dreams into realities is a responsibility we take seriously. We are grateful to be included in creating a positive future."

Marie Napoli, Partner

Long Island Go Red for Women

This organization seeks to increase public awareness of cardiovascular disease and risk factors particularly as they apply to women and the firm is happy to be involved in such a worthy message.

Pencil: Transforming Schools. Together®

We are excited to be supporting this organization, which creates innovative and impactful models of collaboration between the business and education communities by bringing together school needs and business expertise.

Trey Whitfield Foundation, Inc.®

The Foundation aims to motivate, support and encourage children and young adults from across the country pursue their dream of furthering their education. Our commitment to positive youth development aligns with their message.

Save the Children

Through our support of Save the Children, we are part of a program that gives children in the United States and around the world "a healthy start, the opportunity to learn and care when disaster strikes."

Columbus Citizens Foundation

The firm strongly believes in educational scholarships so that no qualified student is denied an education because of financial need.

Annual Food Drive

Every year each of the firm's office locations organizes a food drive to support a local soup kitchen, meals on wheel program or shelter. We were able to donate over 30 large boxes full of non-perishable items last year and we hope the generosity only continues to grow.

Italian Heritage & Culture Committee of New York, Inc.

The firm is happy to support the IHHC-NY's continuing efforts of providing concerts, exhibits, and lectures of the Italian culture to the community.

Holiday Mail for Heroes Program

The firm participates in this wonderful program every year; contributing over 300 cards of thanks and support to members of the armed forces, veterans and their families.

We hope you find this informative and look forward to working alongside you.

NAPOLI SHKOLNIK PLLC
ATTORNEYS AT LAW

360 LEXINGTON AVENUE, 11TH FLOOR
NEW YORK, NEW YORK 10017

(212) 397-1000
NAPOLILAW.COM

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NASSAU

---------- x

THE COUNTY OF NASSAU,

Plaintiff,

- against -

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 PHARMACEUTICALS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC., ENDO HEALTH SOLUTIONS INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN CORPORATION; RUSSELL PORTENOY; PERRY FINE; SCOTT FISHMAN; LYNN WEBSTER, and MICHAEL BELFIORE,

Defendants.

---------- X

Index No.:

VERIFIED COMPLAINT

PLAINTIFF DEMANDS A TRIAL BY JURY

111

115

Plaintiff, the County of Nassau, New York ("Plaintiff," "County," or "Nassau County"), by and through its attorney Carnell T. Foskey, Nassau County, for its Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma Inc.; the Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc. (collectively, "Manufacturers" or "Defendants"); McKesson Corporation, Cardinal Health Inc., Amerisource Drug Corporation (Collectively, "Distributor Defendants" or "Defendants") Russell Portenoy; Perry Fine; Scott Fishman; Lynn Webster; (collectively, "Physicians" or "Defendants") and Michael Belfiore ("Dr. Belfiore") alleges as follows:

INTRODUCTION

1. This case is about one thing: corporate greed. Defendants put their desire for profits above the health and well-being of Nassau County consumers at the cost of Plaintiff.

2. Nassau County spends millions of dollars each year to provide and pay for health care, services, pharmaceutical care and other necessary services and programs on behalf of residents of its County whom are indigent or otherwise eligible for services, including payments through services such as Medicaid for prescription opium painkillers ("opioids") which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants.

3. Nassau County also provides a wide range of other services to its residents, including law enforcement, services for families and children, and public assistance.

4. In recent years, the County of Nassau has been forced to expend exorbitant amounts of money, described further below, due to what is commonly referred to as the "opioid epidemic" and as a direct result of the actions of Defendants.

5. Plaintiff is one of the largest employers on Long Island, employing around 7,500 people. Plaintiff is also responsible for partially funding a medical insurance plan for its employees.

6. Defendants knew that opioids were effective treatments for short-term post-surgical and trauma-related pain, and for palliative (end-of-life) care. Yet they also knew–and had known for years–that opioids were addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as "chronic pain"), and should there not be used except as a last-resort.

7. Defendants further knew–and had known for years–that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.[1, 2]

8. Defendants also knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (not longer than 90 days), and in managed settings (*e.g.*, hospitals), where the risk of addiction and other adverse outcomes was much less significant.

9. Indeed, the U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[3]

---

[1] *See, e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994).

[2] The authoritative *Diagnostic and Statistical Manual of Mental Disorders*, (5th ed. 2013) ("DSM-V") classifies addiction as a spectrum of "substance use disorders" that ranges from misuse and abuse of drugs to addiction. Patients suffer negative consequences wherever they fall on the substance use disorder continuum. Throughout this Complaint, "addiction" refers to this range of substance use disorders.

10. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, and generics like oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, which is why they are regulated as controlled substances.[4] Like heroin, prescription opioids work by binding to receptors on the spinal cord and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which can make them addictive. At certain doses, opioids can slow the user's breathing, causing respiratory depression and death.

11. In order to expand the market for opioids and realize blockbuster profits, Defendants needed to create a sea of change in the medical and public perception that would permit the use of opioids not just for acute and palliative care, but also for long periods of time to treat more common aches and pains, like lower back pain, arthritis, and headaches.

---

[3] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[4] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. Controlled substances are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. 21 U.S.C. § 812. Schedule II drugs may not be dispensed without an original copy of a manually signed prescription from a doctor, which may not be refilled, and filled by a pharmacist who both must be licensed by their state and registered with the DEA. 21 U.S.C. § 829. Opioids that have been categorized as Schedule II drugs include morphine (Avinza, Embeda, Kadian, MS Contin), fentanyl (Duragesic, Actiq, Fentora), methadone, oxycodone (OxyContin, Percocet, Percodan, Tylox), oxymorphone (Opana), and hydromorphone (Dilaudid, Palladone). Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. § 812. Schedule III drugs may not be dispensed without a written or oral prescription, which may not be filled or refilled more than six months after the date of the prescription or be refilled more than five times. 21 U.S.C. § 829. Some opioids had been categorized as Schedule III drugs, including forms of hydrocodone and codeine combined with other drugs, like acetaminophen. However, in October 2013, the FDA, following the recommendation of its advisory panel, reclassified all medications that contain hydrocodone from Schedule III to Schedule II. *See* 21 C.F.R. § 1308.

12. Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s, deepened around 2006, and continues to the present, set out to, and did, reverse the popular and medical understanding of opioids. Chronic opioid therapy—the prescribing of opioids to treat chronic pain long-term—is now commonplace.

13. To accomplish this reversal, Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids long-term use to treat chronic pain (b) deploying sales representatives who visited doctors and other prescribers and delivered misleading messages about the use of opioids (c) recruiting prescribing physicians as paid speakers as a means to secure those physicians' future "brand loyalty" and extend their reach to all physicians; (d) funding, assisting, encouraging, and directing certain doctors, known as "key opinion leaders" ("KOLs"), not only to deliver scripted talks, but also to draft misleading studies, present continuing medical education programs ("CMEs") that were deceptive and lacked balance, and serve on the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; and (e) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups") that developed educational materials and treatment guidelines that were then distributed by Defendants, which urged doctors to prescribe, and patients to use, opioids long-term to treat chronic pain.

14. These efforts, executed, developed, supported, and directed by Defendants, were designed not to present a fair view of how and when opioids could be safely and effectively used, but rather to convince doctors and patients that the benefits of using opioids to treat chronic pain outweighed the risks and that opioids could be used safely by most patients. Defendants and the third parties whom they recruited and supported, all profited handsomely through their dissemination of the

deceptive information. KOLs and Front Groups saw their stature in the medical community elevated dramatically due to Defendants' funding, and Defendants saw an equally dramatic rise in their revenues.

15. Working individually, with, and through these Front Groups and KOLs, Defendants pioneered a new and far broader market for their potent and highly addictive drugs— the chronic pain market. Defendants persuaded doctors and patients that what they had long understood—that opioids are addictive drugs and unsafe in most circumstances for long-term use— was untrue, and to the contrary, that the compassionate treatment of pain *required* opioids. Ignoring the limitations and cautions in their own drugs' labels, Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured their serious risks and adverse outcomes, including the risk of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There was, and is, no reliable scientific evidence to support Defendants' marketing claims, and there was, and is, a wealth of scientific evidence that these claims are simply false. Defendants also deceptively and unfairly marketed the drugs for indications and benefits that were outside of the drugs' labels and not supported by substantial evidence.

16. Even Defendants' KOLs initially were very cautious about whether opioids were appropriate to treat chronic pain. Some of these same KOLs have since recanted their pro-opioid marketing messages and acknowledged that Defendants' marketing went too far. Yet despite the voices of renowned pain specialists, researchers, and physicians who have sounded the alarm on the overprescribing of opioids to treat chronic pain, Defendants continue to disseminate their misleading and unfair marketing claims to this day.

17. Defendants' efforts were wildly successful. The United States is now awash in opioids. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers— enough to medicate every adult in America around the clock for a month. Twenty percent of all doctors' visits in 2010 resulted in the prescription of an opioid, nearly double the rate in 2000. Opioids—once a niche drug—are now the most prescribed class of drugs—more than blood pressure, cholesterol, or anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply. Together, opioids generated $8 billion in revenue for drug companies in 2012.

18. It was Defendants' marketing—and not any medical breakthrough—that rationalized prescribing opioids for chronic pain and opened the floodgates of opioid use and abuse. The result has been catastrophic.

19. According to the U.S. Centers for Disease Control and Prevention ("CDC"), the nation has been swept up in an opioid-induced "public health epidemic."[5] According to the CDC, prescription opioid use contributed to 16,651 overdose deaths nationally in 2010; 16,917 in 2011; and 16,007 in 2012. One Defendant's own 2010 internal data shows that it knew that the use of prescription opioids gave rise to 40% of drug-related emergency department visits in 2010 and 40% of drug poisoning deaths in 2008, and that the trend of opioid poisonings was increasing from 1999-2008. For every death, more than 30 individuals are treated in emergency rooms.

20. In 2014, there were 1,677 opioid-related emergency department admissions in Nassau County, a 75% increase since 2010.[6]

[5] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/t20140429.htm (accessed May 30, 2017)
[6] New York State Department of Health, *New York State Opioid Poisoning, Overdose and Prevention: 2015 Report to the Governor and NYS Legislature*, pp. 34-36.

21. Law enforcement in Nassau County administered Naloxene, a medication used to block the effects of opioids, especially in overdoses, 19 times from 2012 to December 31, 2015.[7]

22. In 2015, alone, there were 111 deaths reported in Nassau County from overdoses involving opioid pain relievers.[8,9]

23. Between 1996 and 2006, the New York State consumption of hydrocodone increased from approximately 2,000 milligrams (mgs) per person to 12,000 mgs per person. Oxycodone consumption increased from approximately 1,000 mgs per person to 16,000 mgs per person. At the same time, health care admissions for opioid analgesic abuse have risen both nationally and in New York State at rates of greater than 300%.

24. In 2016, the opioid Fentanyl surpassed Heroin as the deadliest drug on Long Island. Nearly 500 people died from opioid overdoses on Long Island in 2016, the highest number of deaths to date.[10]

25. The local government and State of New York have taken steps and will foreseeably continue to take steps in efforts to combat the opioid epidemic which has been caused by the actions of the Defendants. These government efforts create an increased cost and spending. As an example, in 2016, Governor Cuomo passed legislation that requires insurance companies to cover inpatient treatment without preapproval, extends emergency room visits from 48 to 72 hours, and adds thousands of addiction treatment slots. All of this creates an increased burden and cost on Medicaid.

26. Due to the continued rise of the opioid epidemic and deaths, Nassau County has taken steps and will continue to take steps to fight the use of opioids and save lives. Since 2012, Nassau

---

[7] *Id.* at 44.
[8] New York State Department of Health, *New York State – County Opioid Quarterly Report for Counties Outside of New York City*, January 2017, p. 61.
[9] The Quarterly Report defines "opioid pain relievers" as "pharmaceutically and illicitly produced opioids such as fentanyl." *Id.* at n.2.
[10] http://www.newsday.com/long-island/nearly-500-people-died-on-li-from-opioid-overdoses-in-2016-1.13387679 (accessed on May 30, 2017)

County has held Narcan training seminars for the public. In recent years Nassau County has created a host of services to assist people suffering from opioid addiction and reduce overdose deaths, including creating the "Heroin Prevention Task force". Again, all of the efforts undertaken by the County of Nassau create a financial burden on the County.

27. The commission of criminal acts to obtain opioids is an inevitable consequence of opioid addiction. One example which received widespread notoriety was the tragic death of an off-duty agent with the Bureau of Alcohol, Tobacco, Firearms and Explosives whom was killed attempting to stop a robbery of a Seaford Pharmacy. It was later learned that the assailant was attempting to steal prescription drugs including oxycodone and Opana.[11]

28. State, County and Local governments, including Nassau County, have begun to warn its residents of a new form of synthetic opioid, Carfentanil, which has made its way into the United States and is responsible for multiple deaths in the Midwest.[12] Nassau County has held free training and information session to teach first responders and the general public about this new, incredibly dangerous, form of opioid. As the opioid epidemic continues to grow, criminal actors will continue to take advantage of the environment created by the Defendants herein.

29. But even these alarming statistics do not fully communicate the toll of prescription opioid abuse on patients and their families.

30. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor-shopping, use of aliases, and criminal means—to satisfy their cravings.

---

[11] http://www.nydailynews.com/new-york/friendly-fire-ex-nassau-killed-hero-atf-agent-drugstore-holdup-sources-article-1.999857 (accessed May 30, 2017).
[12] http://www.newsday.com/long-island/nassau/nassau-issues-warning-about-dangers-of-synthetic-opioid-carfentanil-1.13156187 (accessed May 30, 2017).

31. Efforts by doctors to reverse course for a chronic pain patient already on opioids long-term include managing the physical suffering and psychological distress a patient endures while withdrawing from the drugs. This process is often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that is diverted to supply them. Even though they never would have prescribed opioids in the first place, many doctors feel compelled to continue prescribing opioids to patients who have become dependent on them.

32. According to the CDC, more than 12 million Americans age 12 or older have used prescription painkillers without a prescription in 2010[13], and adolescents are abusing opioids in alarming numbers.

33. Opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on the County and local agencies that address heroin use and addiction. According to the CDC, the percentage of heroin users who also use opioid pain relievers rose from 20.7% in 2002-2004 to 45.2% in 2011-2013. In Nassau County in 2015, there were 141 heroin-related emergency department admissions.[14] Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. It is hard to imagine the powerful pull that would cause a law-abiding, middle-aged person who started on prescription opioids for a back injury to turn to buying, snorting, or injecting heroin, but that is the dark side of opioid abuse and addiction.

34. Dr. Robert DuPont, former director of the National Institute on Drug Abuse, opines that opioids are more destructive than crack cocaine:

---

[13] CDC, *Presxcription Painkiller Overdoses in the US* (Nov. 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/ (accessed May 30, 2017).
[14] http://www.newsday.com/long-island/nassau/nassau-issues-warning-about-dangers-of-synthetic-opioid-carfentanil-1.13156187 (accessed May 30, 2017).

> [Opioid abuse] is building more slowly, but it's much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then. . . . [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of the society to the prescription drug problem.[15]

35. Countless County residents suffer from chronic pain, which takes an enormous toll on their health, their lives, and their families. These residents deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. But Defendants' deceptive and unfair marketing practices deprived County residents and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

36. Defendants' actions are not permitted or excused by the fact that their labels (with the exception of Cephalon's labels for Fentora and Actiq) may have allowed, or did not exclude, the use of opioids for chronic non-cancer pain. The FDA's approval did not give Defendants license to misrepresent the risks, benefits, or superiority of opioids. Indeed, what makes Defendants' efforts particularly nefarious—and dangerous—is that, unlike other prescription drugs marketed unlawfully in the past, opioids are highly addictive controlled substances. Defendants deceptively and unfairly

[15] Transcript, *Use and Abuse of Prescription Painkillers*, The Diane Rehm Show (Apr. 21, 2011), http://thedianerehmshow.org/shows/2011-04-21/use-and-abuse-prescription-painkillers/transcript (accessed May 30, 2017).

engaged a patient base that—physically and psychologically—could not turn away from their drugs, many of whom were not helped by the drugs or were profoundly damaged by them.

37. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were both ubiquitous and highly persuasive; their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians (PCPs), nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the companies' misleading statements. Defendants were also able to callously manipulate what doctors wanted to believe—namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

38. By 2014, nearly two million Americans were either abusing opioid medications or were dependent on opioids.[16] According to the CDC, opioids have created a "public health epidemic" as of 2016.[17]

39. Defendants' marketing campaign has been extremely harmful and has cost American lives – including lives of residents of the County of Nassau. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly 500,000 people died from such overdoses; seventy-eight Americans die everyday from opioid overdoses.[18]

[16] CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids, Addiction and Overdose. Available at http://www.cdc.gov/drugoverdose/opioids/prescribed.html (accessed May 30, 2017).
[17] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse*, (Apr. 29, 2014), http://www.cdc.gov/washington/testimony/2014/ts0140429.htm (accessed May 30, 2017).
[18] CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic.

40. It is estimated that, in 2012, 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.[19]

41. The National Institutes of Health ("NIH") not only recognizes the opioid abuse problem, but also identifies Defendants' "aggressive marketing" as a major cause: "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*."[20] As shown below, the "drastic increases in the number of prescriptions written and dispensed" and the "greater social acceptability for using medications for different purposes " are not really independent causative factors but are in fact the direct result of "the aggressive marketing by pharmaceutical companies."

42. The rising numbers of persons addicted to opioids have led not only to an increase in health care costs to the County, and specifically the Plaintiff, but also a major increase in issues such as drug abuse, diversion,[21] and crimes related to obtaining opioid medications. The County of Nassau has been severely and negatively impacted due to the fraudulent misrepresentations and omissions by Defendants regarding the use and risk related to opioids. In fact, upon information and belief, Defendants have been and continue to be aware of the high levels of diversion of their product.

43. Due to the conduct of the defendants, the commission of criminal acts have been undertaken not only by individuals seeking to obtain opioids, but by physicians themselves. The actions of Defendants have created an environment where select physicians have sought to profit at

[19] Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.
[20] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to- congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed May 30, 2017) (emphasis added).
[21] The CDC defines using or obtaining opioids illegally as "diversion."

the expense of their patients who become addicted to opioid pain medications, often accepting cash payments and ordering unnecessary medical tests, again at the expense of the County.

44. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

JURISDICTION AND VENUE

45. This Court has jurisdiction over this action pursuant to New York Constitution, article VI, § 7(a) and CPLR 301 and 302.

46. Venue is proper in Nassau County pursuant to CPLR 503(a).

47. This action is non-removable because there is incomplete diversity of residents and no substantial federal question is presented.

PARTIES

A. Plaintiff.

48. Nassau County is comprised of about sixty-three towns, cities and villages in Western Long Island, New York. Plaintiff provides a wide range of services on behalf of its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care. As mentioned above, Plaintiff also partially funds a health insurance plan for its approximately 7,500 employees.

49. Plaintiff brings this action on its own behalf and also as subrogee of its employees and residents and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of

its subrogors. In making payments on behalf of its employees and residents, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

B. Defendants.

50. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford Connecticut. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

51. Purdue is primarily engaged in the manufacture, promotion, sale, and distribution of opioids nationally and in Nassau County, including the following:

a. OxyContin (oxycodone hydrochloride extended release) is a Schedule II opioid agonist[22] tablet first approved in 1995 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014,[23] OxyContin was indicated for the "management of moderate to

[22] An opioid agonist is a drug that activates certain opioid receptors in the brain. An antagonist, by contrast, blocks the receptor and can also be used in pain relief or to counter the effect of an opioid overdose.

[23] The labels for OxyContin and other long-acting opioids were amended in response to a 2012 citizens' petition by doctors. The changes were intended to clarify the existing obligation to "make an individualized assessment of patient needs." The petitioners also successfully urged that the revised labels heighten the requirements for boxed label warnings related to addiction, abuse, and misuse by changing "Monitor for signs of misuse, abuse, and addiction" to "[Drug name] exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." Letter from Bob Rappaport, Dir. Ctr. for Drug Evaluations & Res., *Labeling Supplement and PMR [Post-Marketing Research] Required* (Sept. 10, 2013), http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf (accessed May 30, 2017).

severe pain when a continuous, around-the- clock opioid analgesic is needed for an extended period of time."

b. MS Contin (morphine sulfate extended release) is a Schedule II opioid agonist tablet first approved in 1987 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, MS Contin was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

c. Dilaudid (hydromorphone hydrochloride) is a Schedule II opioid agonist first approved in 1984 (injection) and 1992 (oral solution and tablet) and indicated for the "management of pain in patients where an opioid analgesic is appropriate."

d. Dilaudid-HP (hydromorphone hydrochloride) is a Schedule II opioid agonist injection first approved in 1984 and indicated for the "relief of moderate-to-severe pain in opioid-tolerant patients who require larger than usual doses of opioids to provide adequate pain relief."

e. Butrans (buprenorphine) is a Schedule III opioid partial agonist transdermal patch first approved in 2010 and indicated for the "management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Butrans was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time."

f. Hysingla ER (hydrocodone bitrate) is a Schedule II opioid agonist tablet first approved in 2014 and indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

g. Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) is a Schedule II combination product of oxycodone, an opioid agonist, and naloxone, an opioid antagonist, first approved in 2014 and indicated for the management of pain severe enough to require daily, around- the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

52. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

53. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States $635 million—at the time one of the largest settlements with a drug company for marketing misconduct.[24] Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required the company, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement.

[24] https://oig.hhs.gov/publications/docs/press/2007/SemiannualRelfall2007E.pdf (accessed May 30, 2017).

54. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Whales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

55. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

56. Teva USA and Cephalon, Inc. work together closely to market, manufacture, distribute and sell Cephalon products in the United States. Teva USA conducts Teva Ltd.'s sales and marketing activities for Cephalon in the United States and has done so since Teva Ltd.'s October 2011 acquisition of Cephalon. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Nassau County, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. (Teva USA and Cephalon, Inc. collectively are referred to herein as "Cephalon.")

57. Cephalon has been in the business of manufacturing, selling, and distributing the following opioids, nationally and in Nassau County:

a. Actiq (fentanyl citrate) is a Schedule II opioid agonist lozenge (lollipop) first approved in 1998 and indicated for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

b. Fentora (fentanyl citrate) is a Schedule II opioid agonist buccal tablet (similar to plugs of smokeless tobacco) first approved in 2006 and indicated for the "management of breakthrough pain in cancer patients 18 years of age and older

> who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."

58. In November 1998, the FDA granted restricted marketing approval for Actiq, limiting its lawful promotion to cancer patients experiencing pain. The FDA specified that Actiq should not be marketed for off-label uses, stating that the drug must be prescribed solely to cancer patients. In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million in fines, damages, and penalties.

59. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 through 2009 nationally and within the County of Nassau.

60. On September 29, 2008, Cephalon entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services.[25] The agreement, *inter alia*, required Cephalon to send doctors a letter advising them of the settlement terms and gave them a means to report questionable conduct of its sales representatives; disclose payments to doctors on its web site; and regularly certify that the company has an effective compliance program.

61. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as ("f/k/a") Ortho-McNeil- Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica Inc. Defendant Ortho-Mcneil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with

[25] https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (accessed May 30, 2017).

its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc.'s stock, and it corresponds with the FDA regarding Janssen's products. Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceutical's drugs, and Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and Johnson & Johnson collectively are referred to herein as "Janssen.")

62. Janssen manufactures, sells, and distributes a range of medical devices and pharmaceutical drugs in Nassau County and the rest of the nation, including Duragesic (fentanyl), which is a Schedule II opioid agonist transdermal patch first approved in 1990 and indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate."

63. Until January 2015, Janssen also developed, marketed, and sold Nucynta and Nucynta ER:

a. Nucynta ER (tapentadol extended release) is a Schedule II opioid agonist tablet first approved in 2011 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Nucynta ER was indicated for the "management of moderate to severe chronic pain in adults [and] neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." The DPN indication was added in August 2012.

b. Nucynta (tapentadol) is a Schedule II opioid agonist tablet and oral solution first approved in 2008 and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older."

64. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.[26] Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

65. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc. collectively are referred to herein as "Endo.")

66. Endo develops, markets, and sells prescription drugs, including the following opioids, in Nassau County and nationally:

a. Opana ER (oxymorphone hydrochloride extended release) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Opana ER was indicated for the "relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." On June 8, 2017, the FDA requested that Endo

[26] http://www.prnewswire.com/news-releases/depomed-announces-closing-of-acquisition-of-us-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-from-janssen-pharmaceuticals-inc-for-105-billion-300060453.html (accessed May 30, 2017)

Pharmaceuticals remove its opioid medication, reformulated Opana ER (oxymorphone hydrochloride), from the market.[27]

b. Opana (oxymorphone hydrochloride) is a Schedule II opioid agonist tablet first approved in 2006 and indicated for the "relief of moderate to severe acute pain where the use of an opioid is appropriate."

c. Percodan (oxycodone hydrochloride and aspirin) is a Schedule II opioid agonist tablet first approved in 1950 and first marketed by Endo in 2004 and indicated for the "management of moderate to moderately severe pain."

d. Percocet (oxycodone hydrochloride and acetaminophen) is a Schedule II opioid agonist tablet first approved in 1999 and first marketed by Endo in 2006 and indicated for the "relief of moderate to moderately severe pain."[28]

67. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and alone accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids nationally and in Nassau County, both itself and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

68. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in March 2015. Prior to that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012; the combined company changed its name to Actavis, Inc. in

[27] *FDA Requests Removal of Opana ER for Risks Related to Abuse.* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[28] In addition, Endo marketed Zydone (hydrocodone bitartrate and acetaminophen), a Schedule III opioid agonist tablet indicated for the "relief of moderate to moderately severe pain," from 1998 through 2013. The FDA's website indicates this product is currently discontinued, but it appears on Endo's own website.

January 2013 and then to Actavis plc in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter collectively are referred to as "Actavis.")

69. Actavis engages in the business of marketing and selling opioids in Nassau County and across the country, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Kadian (morphine sulfate extended release) is a Schedule II opioid agonist capsule first approved in 1996 and indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Prior to April 2014, Kadian was indicated for the "management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

70. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California.

71. Defendant McKesson had a net income in excess of $1.5 Billion in 2015.

72. Defendant McKesson distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including New York State and the County of Nassau.

73. Upon information and belief, defendant McKesson is a pharmaceutical distributor licensed to do business in New York State.

74. Defendant McKesson is the largest pharmaceutical distributor in North America.

75. Upon information and belief, McKesson delivers one-third of all pharmaceuticals used in North America.

76. Defendant McKesson does substantial business in the State of New York and Nassau County.

77. Defendant Cardinal Health Inc. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio.

78. Defendant Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including New York and Nassau County.

79. Upon information and belief, defendant Cardinal is a pharmaceutical distributor licensed to do business in New York State.

80. Defendant Cardinal does substantial business in the State of New York and Nassau County.

81. Upon information and belief, defendant Cardinal is one of the largest distributors of opioid pain medications in Nassau Country, including New York State and the County of Nassau.

82. Upon information and belief, Defendant AmerisourceBergen Drug Corporation ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania.

83. Defendant Amerisource does substantial business in the State of New York and Nassau County.

84. Upon information and belief, defendant Amerisource is a pharmaceutical distributor licensed to do business in New York State.

85. Defendant Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including New York State in Nassau County.

86. Upon information and belief, defendant Amerisource is one of the largest distributors of opioid pain medications in the Country, including New York State.

87. The three pharmaceutical distributor defendants, Cardinal, Amerisource, and Mckesson (hereinafter "Distributor Defendants") are three of the largest opioid distributors in Nassau County.

88. The Distributor Defendants purchased opioids from manufacturers, such as the named defendants herein, and sold them to pharmacies throughout Nassau County .

89. The Distributor Defendants played an integral role in the chain of opioids being distributed throughout Nassau County.

90. Pursuant to Section 80.22 of the New York Codes, Rules and Regulations, entitled "Suspicious Orders," distributors such as the defendants are required to:

> [E]stablish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

91. From 2007 to 2016 pharmaceutical distributors, including Defendants, distributed at least 5,472,578 grams of opioid pharmaceuticals to retail providers such as pharmacies in Nassau County.

92. This number only represents opioids distributed directly to retailers.

93. This number shows an alarming and suspicious rise in the ordering of opioid pain medications by retailers throughout Nassau County.

94. For example, in 2007 there were 190,081 grams of OxyCodone distributed to retailers in Nassau County. This number rose every year through 2011, when it more than doubled to 400,267.89 grams.

95. The Distributor Defendants were each on notice that the controlled substances they distributed or prescribed were the kinds that were susceptible to diversion for illegal purposes, abused, overused, and otherwise sought for illegal, unhealthy and problematic purposes.

96. The Distributor Defendants were each on notice that there was an alarming and suspicious rise in distributing opioids to retailers within Nassau County during this time period.

97. As entities involved in the distribution of opioid medications, Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under New York Law.

98. The Distributor Defendants had a duty to notice suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies including the DEA and the New York State Department of Health.

99. The Distributor Defendants knew or should have known that they were supplying vast amounts of dangerous drugs in Nassau County that were already facing abuse, diversion, misuse, and other problems associated with the opioid epidemic.

100. The Distributor Defendants failed in their duty to take any action to prevent or reduce the distribution of these drugs.

101. The Distributor Defendants were in a unique position and had a duty to inspect, report, or otherwise limit the flow of these drugs to Nassau County.

102. The Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

103. The Distributor Defendants have displayed a continuing pattern of failing to submit suspicious order reports.

104. In 2008, McKesson paid a $13.25 million fine to settle similar claims regarding suspicious orders from internet pharmacies.[29]

105. Despite these prior penalties, McKesson's pattern of failing to report suspicious orders continued for many years.

106. According to the DEA, McKesson "supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills" during the time in question, and "frequently misused products that are part of the current opioid epidemic."[30]

107. On January 17, 2017, the DEA announced that McKesson had agreed to pay a record $150 million fine and suspend the sale of controlled substances from distribution centers in several states.[31]

108. In 2008, defendant Cardinal paid a $34 million penalty to resolve allegations that it failed to report suspicious opioid orders.[32]

109. Despite this past penalty, in 2017, it was announced that defendant Cardinal agreed to a $44 million fine to "resolve allegations that it failed to alert the Drug Enforcement Agency to suspicious orders of powerful narcotics by pharmacies in Florida, Maryland, and New York.[33]

---

[29] http://www.wvgazettemail.com/news-health/20161218/suspicious-drug-order-rules-never-enforced-by-state (accessed May 30, 2017).
[30] https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders (accessed May 30, 2017).
[31] *Id.*
[32] https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0 (access May 30, 2017).

110. Defendant AmeriSource faced a criminal inquiry "into its oversight of painkiller sales" in 2012.[34] They have paid out fines for similar claims to the state of West Virginia.

111. Despite the charges, fines, and penalties brought against the Distributor Defendants in the past, they continued to fail to report suspicious orders or prevent the flow of prescription opioids, including into Nassau County.

112. The Distributor Defendants are also members of the Healthcare Distribution Management Association ("HDMA"). The HDMA created "Industry Compliance Guidelines" which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that "[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

113. Between the years in question, including 2007 through 2016, the Distributor Defendants have shipped millions of doses of highly addictive controlled opioid pain killers into Nassau County.

114. Many of these orders should have been stopped, or at the very least, investigated as potential suspicious orders.

115. The sheer volume of the increase in opioid pain medications, including OxyCodone, being distributed to retailers, should have put the Distributor Defendants on notice to investigate and report such orders.

116. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in Nassau County.

---

[33] https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.7049c4431465 (accessed on May 30, 2017).
[34] http://www.nytimes.com/2013/06/12/business/walgreen-to-pay-80-million-settlement-over-painkiller-sales.html (accessed on May 30, 2017).

117. Upon information and belief, the Distributor Defendants did not refuse to ship or supply any opioid medications to any pharmacy in Nassau County from 2007 to the present.

118. The Defendant Distributors knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of Nassau County.

119. The Defendant Distributors also paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications within Nassau County.

120. The Distributor Defendants made substantial profits from the opioids sold in Nassau County.

121. The Distributor Defendants violated New York State Department of Health rules and regulations for distributors, including the aforementioned section 80.22, by failing to properly report suspicious orders.

122. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the residents of Nassau County.

123. By the actions and inactions described above, the Distributor Defendants caused great harm to the County of Nassau.

124. Russell Portenoy, M.D., is an individual residing in New York. Defendant Dr. Portenoy is a physician licensed to practice medicine in the state of New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in Nassau County.

125. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in Nassau County.

126. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was instrumental in promoting opioids for sale and distribution nationally and in Nassau County.

127. Lynn Webster, M.D., is an individual residing in Utah. Dr. Webster was instrumental in promoting opioids for sale and distribution nationally and in Nassau County.

128. Michael Belfiore, D.O., is a physician licensed to practice medicine in the State of New York with a practice located at 2209 Merrick Road, #100, Merrick New York 11566.

129. Dr. Belfiore is a Nassau County physician licensed to practice medicine in the State of New York, whose office is located in the town of Merrick, in the County of Nassau. He practiced as a general practitioner and dermatologist. Dr. Belfiore was charged on October 8th, 2014 with illegally distributing oxycodone after DEA authorities learned he had written about 5,000 prescriptions, or 600,000 oxycodone pills, in a three-year period. He was charged with writing prescriptions "with no legitimate medical need."[35]

130. In response to the charges he is facing, Dr. Belfiore blames the pharmaceutical industry for his conduct. Through his attorney, Dr. Belfiore maintains that he, "like many other doctors and their patients, is a victim of an opioid epidemic created by [Big Pharma companies] which encouraged the aggressive prescribing of opioids for chronic pain."[36]

131. Dr. Belfiore, for his own profit, greatly contributed to the widespread opioid epidemic of Nassau County and Long Island.

FACTS RELEVANT TO ALL CAUSES OF ACTION

A. Background on Pain Medicine.

1. Safe and Effective Treatment of Chronic Pain Centers on Informed Risk Management.

132. The practice of medicine centers on informed risk management. Prescribers must weigh the potential risks and benefits of each treatment option, as well as the risk of non-treatment.

[35] http://www.newsday.com/long-island/nassau/merrick-doctor-was-illegally-prescribing-painkillers-feds-say-1.9480169 (accessed May 30, 2017).
[36] http://liherald.com/stories/Merrick-doctor-wants-pain-pill-case-tossed,87038 (accessed May 30, 2017).

133. Accordingly, the safe and effective treatment of chronic pain requires that a physician be able to weigh the relative risks of prescribing opioids against both (a) the relative benefits that may be expected during the course of opioid treatment and (b) the risks and benefits of alternatives.

134. This bedrock principle of full disclosure is particularly important in the context of chronic opioid therapy because of the risk that patients will become physically and psychologically dependent on the drugs, finding it difficult to manage or terminate their use.

135. The FDA-approved drug labels on each of Defendants' opioids do not attempt to advise physicians how to maximize the benefits and minimize the risks for patients on long-term chronic opioid therapy. The labels contain no dosing cap above which it would be unsafe for any doctor to prescribe to any patient. Nor do any of the labels provide a duration limit, after which the risks to a patient might increase. Thus, doctors and patients rely more heavily on educational materials such as treatment guidelines, CMEs, and scientific and patient education articles and websites to inform their treatment decisions.

2. Opioid Use Is Associated with Known and Substantial Risks.

136. Opium has been recognized as a tool to relieve pain for millennia; so has the magnitude of its potential for abuse, addiction and its dangers. Opioids are related to illegal drugs like opium and heroin. In fact, types of fentanyl, a widely-distributed opioid in the United States, have now been made illegal in China.

137. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants and beverages. By 1900, an estimated 300,000 people

were addicted to opioids in the United States.[37] Many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

138. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and "[s]erious, life-threatening, or fatal respiratory depression," as the result of an excessive dose.

139. Studies and articles from the 1970s and 1980s also made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, and even prohibited, the use of opioid therapy for chronic pain.

140. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the patient had been using opioids.

141. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to

[37] Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[38] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

142. Dr. Andrew Kolodny, Chief Medical Officer for Phoenix House, a national addiction treatment program, has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[39] A patient's fear of the unpleasant effects of discontinuing opioids combined with the negative reinforcement during a period of actual withdrawal can drive a patient to seek further opioid treatment—even where ineffective or detrimental to quality of life—simply to avoid the deeply unpleasant effects of withdrawal.

143. Patients that receive high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to an overdose even when opioids are taken as recommended.

144. Further, "a potential side effect from chronic use [of opioids] can be abuse and addiction . . . . [i]n fact, correct use and abuse of these agents are not polar opposites—they are complex, inter-related phenomena."[40] It is very difficult to tell whether a patient is physically dependent, psychologically dependent, or addicted. Drug-seeking behaviors, which are signs of

---

[38] M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

[39] David Montero, *Actor's Death Sows Doubt Among O.C.'s Recovering Opioid Addicts*, The Orange Cnty. Reg. (Feb. 3, 2014), http://www.ocregister.com/articles/heroin-600148-shaffer-hoffman.html (accessed May 30, 2017).

[40] Wilson M. Compton & Nora D. Volkow, *Major Increases in Opioid Analgesic Abuse in the United States: Concerns and Strategies*, 81(2) Drug & Alcohol Dependence 103, 106 (2006).

addiction, will exist and emerge when opioids are suddenly not available, the dose is no longer effective, or tapering of a dose is undertaken too quickly.

145. Studies have shown that between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.[41]

146. Each of these risks and adverse effects—dependence, tolerance, and addiction—is fully disclosed in the labels for each of Defendants' opioids (though, as described below, not in Defendants' marketing).[42] Prior to Defendants' deceptive marketing scheme, each of these risks was well-recognized by doctors and seen as a reason to use opioids to treat chronic pain sparingly and only after other treatments had failed.

147. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

148. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them with short-acting, rapid- onset opioids for episodic pain.

149. Defendant Purdue was aware that its drug OxyContin did not provide pain relief for up to 12 hours. Purdue was also aware of the risk that patients would then take additional pain

[41] Joseph A. Boscarino et al., *Risk factors for drug daependence among out-patients on opioid therapy in a large US health-care system*, 105(10) Addiction 1776 (2010); Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3) Journal of Addictive Diseases 185 (2011).

[42] For example, Purdue's OxyContin label (October 5, 2011) states: "Physical dependence and tolerance are not unusual during chronic opioid therapy."

medications, beyond what was prescribed, to make of up for that gap in time. Despite this knowledge, Purdue continued to market OxyContin as lasting for 12 hours.

150. While it was once thought that long-acting opioids would not be as susceptible to abuse and addiction as short-acting ones, this view has been discredited. OxyContin's label now states, as do all labels of Schedule II long-acting opioids, that the drug "exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death." The FDA has required extended release and long-acting opioids to adopt "Risk Evaluation Mitigation Strateg[ies]" on the basis that they present "a serious public health crisis of addiction, overdose, and death."[43]

151. In 2013, in response to a petition to restrict the labels of long-acting opioid products, the FDA noted the "grave risks" of opioids, "the most well-known of which include addiction, overdose, and even death."[44] The FDA further warned that "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death."[45] The FDA required that—going forward—opioid makers of long-acting formulations clearly communicate these risks in their labels. Thus, the FDA confirmed what had previously been accepted practice in the treatment of pain— that the adverse outcomes from opioid use include "addiction, unintentional overdose, and death" and that long-acting or extended release opioids "should be used ***only when alternative treatments are inadequate***."[46]

152. Notably, in reaching its conclusion, the FDA did not rely on new or otherwise previously unavailable scientific studies regarding the properties or effects of opioids.

---

[43] FDA, *Risk Evaluation and Mitigation Strategy (REMS) for Extended-Release and Long-Acting Opioids* (last updated Oct. 9, 2014), http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm (accessed May 30, 2017).

[44] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[45] *Id.*

[46] *Id.* at 7 (emphasis in original).

153. The FDA-approved labels on each of Defendant's opioids do not attempt to advise physicians on how to maximize the benefits and minimize the risks for patients on long term opioid therapy. The labels contain no dosage cap above which it would be unsafe to prescribe to any patient. Nor do they provide a duration limit. Doctors and patients rely heavily on education materials, such as treatment guidelines, CMEs, and scientific and patient education articles and websites, to inform their treatment decisions.

154. On July 25, 2012, the Physician For Responsible Opioid Prescribing ("PROP"), a non-profit organization made up of doctors and other health care professionals, petitioned the FDA to change the labeling of opioid medications. The petition was signed by thirty-seven physicians located nationwide. In its letter to the FDA, the group stated that "an increasing body of medical literature suggests that long term-use of opioids may be neither safe nor effective for many patients, especially when prescribed in high doses."[47]

155. In its petition, PROP also stated that "many clinicians are under the false impression that chronic opioid therapy (COT) is an evidence-based treatment for chronic non-cancer pain" and that "these misconceptions lead to overprescribing and high dose prescribing." It was also their opinion that "the current label on opioid analgesics does not comply with [FDA law]".

156. As the basis for its petition, PROP provided "Statements of Scientific Basis for Petition" which provided a list of detailed reports and studies proving the risks of opioid medications, the high risk of addiction, the exaggerated and false benefits, and further medically backed reasons to change the labelling of opioid medications to reduce prescribing.

157. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids,

[47] July 25, 2012 letter from PROP to FDA, accessed at http://www.citizen.org/documents/2048.pdf on May 30, 2017.

including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life- threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."[48] The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks on their labels.

158. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release for opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.[49]

159. The facts on which the FDA relied in 2013 and 2016 were well known to Defendants for many years since they began marketing these drugs.

3. Long-Term Opioid Use Benefits Are Unproven and Contradicted.

160. Despite the fact that opioids are now routinely prescribed, there has never been evidence of their safety and efficacy for long-term use.

161. Defendants have always been aware of these gaps in knowledge. While promoting opioids to treat chronic pain, Defendants have failed to disclose the lack of evidence to support their long-term use and have failed to disclose the contradictory evidence that chronic opioid therapy actually makes patients sicker.

---

[48] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. *Physicians for Responsible Opioid Prescribing,* Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013) (emphasis in original).

[49] FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death. Available at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm (accessed May 30, 2017).

162. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. The first random, placebo-controlled studies appeared in the 1990s, and revealed evidence only for short-term efficacy and only in a minority of patients.[50]

163. A 2004 report reviewed 213 randomized, controlled trials of treatments for cancer pain and showed that, while opioids had short-term efficacy, the data was insufficient to establish long-term effectiveness. Subsequent reviews of the use of opioids for cancer and non-cancer pain consistently note the lack of data to assess long-term outcomes. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy for back pain and that evidence did not allow judgments regarding long-term use. Similarly, a 2011 systematic review of studies for non-cancer pain found that evidence of long-term efficacy is poor. One year later, a similar review reported poor evidence of long-term efficacy for morphine, tramadol, and oxycodone, and fair evidence for transdermal fentanyl (approved only for use for cancer pain).

164. On the contrary, evidence exists to show that opioid drugs are not effective to treat chronic pain, and may worsen patients' health. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Most notably, it stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[51] Another review of evidence relating to the use of opioids for chronic pain found that

[50] Nathaniel Katz, *Opioids: After Thousands of Years, Still Getting to Know You*, 23(4) Clin J. Pain 303 (2007); Roger Chou et al., *Research Gaps on Use of Opioids for Chronic Noncancer Pain*, 10(2) J. Pain 147 (2009).

[51] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids.

up to 22.9% of patients in opioid trials dropped out before the study began because of the intolerable effects of opioids, and that the evidence of pain relief over time was weak.

165. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

166. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

167. As a pain specialist noted in an article titled *Are We Making Pain Patients Worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[52]

168. This is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Conversely, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not help patients return to work or to physical activity. This is due partly to addiction and other side effects.

169. As many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. A survey by the National Headache Foundation

---

Karen H. Seal, *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

[52] Andrea Rubenstein, *Are we making pain patients worse?*, Sonoma Medicine (Fall 2009).

found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

170. The lack of evidence for the efficacy of opioid use long-term has been well-documented nationally in the context of workers' compensation claims, where some of the most detailed data exists. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, taking an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids, as the first treatment for a workplace injury, doubled the average length of the claim.

4. Defendants' Impact on the Perception and Prescribing of Opioids.

171. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

172. In 1986, the World Health Organization ("WHO") published an "analgesic ladder" for the treatment of cancer pain.[53] The WHO recommended treatment with over-the- counter or prescription acetaminophen or non-steroidal anti-inflammatory drugs ("NSAIDs") first, and then the use of unscheduled or combination opioids, and then stronger (Schedule II or III) opioids if pain persisted. The WHO ladder pertained only to the treatment of cancer pain, and did not contemplate the use of narcotic opioids for chronic pain—because the use of opioids for chronic pain was not considered appropriate medical practice at the time.

[53] http://apps.who.int/iris/bitstream/10665/43944/1/9241561009_eng.pdf (accessed May 30, 2017)

173. Studies and articles from the 1970s and 1980s made the reasons to avoid opioids clear. Scientists observed negative outcomes from long-term opioid therapy in pain management programs: opioids' mixed record in reducing pain long-term and failure to improve patients' function; greater pain complaints as most patients developed tolerance to opioids; opioid patients' diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

174. In 1986, Defendant Dr. Russell Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, while at the same time serving as a top spokesperson for drug companies, published an article reporting that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy."[54]

175. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

> The traditional approach to chronic nonmalignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. *Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*[55]

---

[54] Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases*, 25(2) Pain 171 (1986).

[55] Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt. 247 (1994) (emphasis added).

According to Portenoy, these problems could constitute "compelling reasons to reject long term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain."[56]

176. For the reasons outlined by Dr. Portenoy, and in the words of one researcher from the Harvard Medical School, "it did not enter [doctors'] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids."[57] Defendants changed that perception.

B. Defendants Promoted Their Branded Products Through Direct Marketing to Prescribers and Consumers.

177. Defendants' direct marketing proceeded on two tracks, serving two related purposes. First, Defendants worked through branded and unbranded marketing to build confidence in long-term opioid use by overstating its benefits and downplaying its risks, thereby expanding the chronic pain market. In addition, Defendants worked through their own staffs of sales representatives, physician speakers whom those representatives recruited, and advertising in medical journals to claim their share of that broader market. Defendants directed all of this activity through carefully designed marketing plans that were based on extensive research into prescriber habits and the efficacy of particular sales approaches and messages.

1. Defendants Relied Upon Branded Advertisements.

178. Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals

[56] *Id.*

[57] Igor Kissin, *Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?*, 6 J. Pain Research 513, 514 (2013) (quoting Loeser JD, *Five crises in pain management*, 20(1) Pain Clinical Updates 1-4 (2012).

with wider medical audiences, such as the *Journal of the American Medical Association*. Defendants' advertising budgets peaked in 2011, when they collectively spent more than $14 million on the medical journal advertising of opioids, nearly triple what they spent in 2001. The 2011 total includes $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[58]

179. A number of these branded advertisements deceptively portrayed the benefits of opioid therapy for chronic pain. As just one example, a 2005 Purdue advertisement for OxyContin that ran in the *Journal of Pain* touted the drug as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "There Can Be Life With Relief." This depiction falsely implied that OxyContin provides both effective long-term pain relief and functional improvement, claims that, as described below, are unsubstantiated and contradicted in medical literature.

2. Defendants Relied Upon Their Sales Forces and Recruited Physician Speakers.

180. Each Defendant promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual physicians and their staff in their offices—and small group speaker programs. By establishing close relationships with doctors, Defendants' sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to address individual prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships, with Actavis even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors.

181. Defendants developed sophisticated plans to select prescribers for sales visits based on their specialties and prescribing habits. In accordance with common industry practice, Defendants

[58] In 2011, Actavis spent less than $100,000 on such advertising, and Cephalon spent nothing. These companies' medical journal advertising peaked earlier, with Actavis spending $11.7 million in 2005, and Cephalon spending about $2 million in each of 2007 and 2008.

purchase and closely analyze prescription sales data from IMS Health. This data allows them to precisely track the rates of initial prescribing and renewal by individual doctors, which in turn allows them to target, tailor, and monitor the impact of their appeals.

182. Defendants, in particular, relied upon "influence mapping," *i.e.*., using decile rankings or similar breakdowns to identify the high-volume prescribers on whom detailing would have the greatest sales impact. Endo, for example, identified prescribers representing 30% of its nationwide sales volume and planned to visit these physicians three times per month. Defendants also closely monitored doctors' prescribing after a sales representative's visit to allow them to refine their planning and messaging and to evaluate and compensate their detailers.

183. Defendants' sales representatives have visited hundreds of thousands of doctors, including thousands of visits to Nassau County prescribers, and as described herein, spread misinformation regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. This misinformation includes deceptive and unfair claims regarding the risks of opioids for chronic pain, particularly the risks of addiction, withdrawal, and high doses, as well as the benefits.

184. Each Defendant carefully trained its sales representatives to deliver company-approved messages designed to generate prescriptions of that company's drugs specifically, and opioids in general. Pharmaceutical companies exactingly direct and monitor their sales representatives—through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and other means—to ensure that individual detailers actually deliver the desired messages and do not veer off-script. Pharmaceutical companies likewise require their detailers to deploy sales aids reviewed, approved, and supplied by the company and forbid them to use, in industry parlance, "homemade bread"—*i.e.*, promotional materials not approved by the company's marketing and compliance departments. Sales representatives' adherence to their corporate training is typically included in their work agreements.

Departing from their company's approved messaging can, and does, lead to severe consequences including termination of employment.

185. Besides carefully training their sales representatives, Defendants used surveys of physicians—conducted by third-party research firms—to assess how well their core messages came across to prescribers.

186. In addition to making sales calls, Defendants' detailers also identified doctors to serve, for payment, on Defendants' speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. Defendants almost always selected physicians who were "product loyalists," as they were sure to be asked whether they prescribe the drug themselves. Endo, for instance, sought to use specialists in pain medicine—including high prescribers of its drugs—as local "thought leaders" to market Opana ER to primary care doctors. Such invitations are lucrative to the physicians selected for these bureaus; honorarium rates range from $800 to $2,000 per program, depending on the type of event, speaker training is typically compensated at $500 per hour.

187. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe, or increase their prescriptions of, a particular drug; a forum in which to further market to the speaker him or herself; and an opportunity to market to the speaker's peers. Defendants grade their speakers and future opportunities are based on speaking performance, post-program sales, and product usage. Defendants also track the prescribing of event attendees, with Endo noting that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before." It would make little sense for Defendants to devote significant resources to programs that did not increase their sales.

188. Like the sales representatives who select them, speakers are expected to stay "on message"—indeed, they agree in writing to follow the slide decks provided to them. Endo's speaker rules, for example, provide that "all slides must be presented in their entirety and without alterations . .

. and in sequence." This is important because the FDA regards promotional talks as part of product labeling, and requires their submission for review. Speakers thus give the appearance of providing independent, unbiased presentations on opioids, when in fact they are presenting a script prepared by Defendants' marketing departments. Although these meal-based speaker events are more expensive to host, and typically have lower attendance than CMEs, they are subject to less professional scrutiny and thus afford Defendants greater freedom in the messages they present.

189. Defendants devoted massive resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

190. Defendants have spent hundreds of millions of dollars promoting their opioids through their respective sales forces because they understand that detailers' sales pitches are effective. Numerous studies indicate that marketing can and does impact doctors' prescribing habits,[59] and face-to-face detailing has the highest influence on intent to prescribe. Defendants could see this phenomenon at work not only in the aggregate, as their sales climbed with their promotional spending,

[59] *See, e.g.,* Puneet Manchanda & Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); *see also* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

but also at the level of individual prescribers whom they targeted for detailing, and who responded by prescribing more of Defendants' drugs.

3. Defendants Directed These Promotional Efforts Through Detailed Marketing Plans.

191. Defendants guided their efforts to expand opioid prescribing through comprehensive marketing and business plans for each drug. These documents, based on the companies' extensive market research, laid out ambitious plans to bring in new prescribers and increase overall prescribing of Defendants' opioids.

a. Targeting categories of prescribers

192. Defendants targeted, by zip codes and other local boundaries, individual health care providers for detailing. Defendants chose their targets based on the potential for persuading a provider to prescribe, ease of in-person access, and the likelihood of higher numbers of prescriptions at higher doses, with no correlation to demonstrated need or demand for opioid therapy, or to risk of abuse.

193. Collectively, Defendants' marketing plans evince dual strategies, which often operated parallel to one another. Defendants' sales representatives continued to focus their detailing efforts on pain specialists and anesthesiologists, the highest-volume prescribers of opioids and, as a group, more educated than other practitioners about opioids' risks and benefits. Seeking to develop market share and expand sales, however, Defendants also targeted increasing numbers and types of prescribers for marketing.

194. This expanded market of prescribers was, as a group, less informed about opioids and, as market research concluded, more susceptible to Defendants' marketing messages. These prescribers included nurse practitioners and physician assistants who, a 2012 Endo business plan noted, were "share acquisition" opportunities because they were "3x times more responsive than MDs to details" and wrote "96% of [their] prescriptions . . . without physician consult."

195. The expanded market also included internists and general practitioners who were low- to mid-volume prescribers. Actavis, for example, rolled out a plan in 2008 to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

b. Increasing "direct to consumer" marketing

196. Defendants knew that physicians were more likely to prescribe their branded medications when patients asked for those medications. Endo's research, for example, found that such communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physician's office, as well as employer and workers' compensation plan initiatives to, as Endo put it, "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss."

197. Defendants also knew that one of the largest obstacles to patients starting and remaining on their branded opioids—including by switching from a competitor's drug—was out- of-pocket cost. They recognized they could overcome this obstacle by providing patients financial assistance with their insurance co-payments, and each of the Defendants did so through vouchers and coupons distributed during detailing visits with prescribers. A 2008 Actavis business review, for example, highlighted co-pay assistance, good for up to $600 per patient per year, as a way to drive conversions to Kadian from competitor drugs like Avinza and MS Contin. In 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

c. Differentiating each brand

198. Purdue's OxyContin was the clear market leader in prescription opioid therapy, with 30% of the market for analgesic drugs in 2012. However, by 2010, Defendants had begun facing increasing pushback from the medical community and regulators based on the growing problems of opioid addiction and abuse. Both market conditions prompted Defendants to pursue product differentiation strategies—particularly an emphasis on their products being less subject to diversion, abuse, and addiction—as a means of grabbing market share from Purdue and other competitors.

199. Endo, for example, tracked in detail prescriber "switching" from OxyContin to Opana ER. Actavis and Janssen did the same for switches to Kadian and Nucynta ER, respectively. Pressure to stand out among other drugs resulted in Defendants identifying marketing themes that thereafter were reflected in Defendants' deceptive and harmful messages to physicians and consumers. A 2008 Janssen plan emphasized "value" messaging in support of Nucynta ER, including claims of less dose escalation, lower toxicity, fewer withdrawal symptoms, and less dependence, and a 2009 Opana ER market research report focused on greater potency and lower abuse potential of Opana ER vis-à-vis OxyContin.

d. Moving beyond office visits

200. Defendants sought to reach additional prescribers by expanding beyond traditional sales calls and speaker events to new channels for their messages. For their sales forces, these included marketing to prescribers through voice mail, postcards, and email—so- called "e-detailing." Defendants also created new platforms for their speakers by implementing "peer to peer" programs such as teleconferences and webinars that were available to prescribers nationally. These programs allowed Defendants to use this more seemingly credible vehicle to market to, among other hard-to-reach audiences, prescribers at hospitals, academic centers, and other locations that limit or prohibit in-

person detailing. Employing these new approaches, each Defendant relied heavily on speakers to promote its drugs.

4. Defendants Marketed Opioids in Nassau County Using the Same Strategies and Messages They Employed Nationwide.

201. Defendants employed the same marketing plans and strategies and deployed the same messages in Nassau County as they did nationwide.

202. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

203. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide desks, and supervisors traveled with them periodically to check on both their performance and compliance.

204. As they did nationwide, Defendants extensively tracked the prescribing behavior of County-area health care providers and used that data to target their detailing and speaker- recruiting efforts. Top prescribers were profiled at the city, region, zip code, and sometimes facility levels, with information about their specialty, prescribing patterns (including product and dose), product loyalty and refill history. Providers' prescribing volume was ranked and sorted into deciles.

205. As described herein, misrepresentations and deceptions regarding the risks, benefits, and superiority of opioid use to treat chronic pain were part and parcel of Defendants' marketing campaigns in Nassau County.

C. Defendants Used "Unbranded" Marketing to Evade Regulations and Consumer Protection Laws.

206. In addition to their direct marketing efforts, Defendants used unbranded, third- party marketing, which they deployed as part of their national marketing strategies for their branded drugs. Each Defendant executed these strategies through a network of third-party KOLs and Front Groups, with which it acted in concert by funding, assisting, encouraging, and directing their efforts. At the same time, Defendants exercised substantial control over the content of the messages third parties generated and disseminated, and distributed certain of those materials themselves. As with their other marketing strategies, Defendants' unbranded marketing created, and relied upon, an appearance of independence and credibility that was undeserved but central to its effectiveness. Unlike their direct promotional activities, Defendants' unbranded marketing allowed them to evade the oversight of federal regulators and gave them greater freedom to expand their deceptive messages.

1. Regulations Governing Branded Promotion Require that it Be Truthful, Balanced, and Supported by Substantial Evidence.

207. Drug companies that make, market, and distribute opioids are subject to generally applicable rules requiring truthful marketing of prescription drugs. A drug company's branded marketing, which identifies and promotes a specific drug, must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.[60] The regulatory framework governing the marketing of specific drugs reflects a public policy designed to ensure that drug companies, which are best suited to understand the properties and effects of their drugs, are responsible for providing

[60] 21 U.S.C. § 352(a); 21 C.F.R. §§ 1.21(a), 202.1(e)(3), 202.1(e)(6).

prescribers with the information they need to accurately assess the risks and benefits of drugs for their patients.

208. Further, the Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the sale in interstate commerce of drugs that are "misbranded." A drug is "misbranded" if it lacks "adequate directions for use" or if the label is false or misleading "in any particular."[61] "Adequate directions for use" are directions "under which the layman can use a drug safely and for the purposes for which it is intended."[62] "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[63] "The term "accompanying" is interpreted broadly to include promotional materials—posters, websites, brochures, books, and the like—disseminated by or on behalf of the manufacturer of the drug.[64] Thus, Defendants' promotional materials are part of their drugs' labels and are required to be accurate, balanced, and not misleading.

209. Labeling is misleading if it is not based on substantial evidence, if it materially misrepresents the benefits of the drug, or if it omits material information about or minimizes the frequency or severity of a product's risks. "The most serious risks set forth in a product's labeling are generally material to ***any*** presentation of efficacy." The FDA notes that "[b]ecause people expect to see risk information, there is no reason for them to imagine that the product has important risks that have been omitted . . . especially if some risks are included."[65] Promotion that fails to present the most important risks of the drug as prominently as its benefits lacks fair balance and is therefore deceptive.

---

[61] 21 U.S.C. §§ 352.
[62] 21 C.F.R. § 201.5.
[63] 21 U.S.C. § 321(m).
[64] *See id.*
[65] FDA, *Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion*, May 2009, at 14.

210. It is also illegal for drug companies to distribute materials that exclude contrary evidence or information about the drug's safety or efficacy or present conclusions that "clearly cannot be supported by the results of the study."[66] Further, drug companies must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[67]

211. While the FDA must approve a drug's label, it is the drug company's responsibility to ensure that the material in its label is accurate and complete and is updated to reflect any new information.[68] Promotional materials also must be submitted to the FDA when they are first used or disseminated. The FDA does not have to approve these materials in advance; if, upon review, the FDA determines that materials marketing a drug are misleading, it can issue an untitled letter or warning letter. The FDA uses untitled letters for violations such as overstating the effectiveness of the drug or making claims without context or balanced information. Warning letters address promotions involving safety or health risks and indicate the FDA may take further enforcement action.

2. Defendants Deployed Front Groups and Doctors to Disseminate Unbranded Information on Their Behalf.

212. Drug companies market both directly and indirectly, using third party validators (such as scientists, physicians, patient or professional organizations) that appear to be independent and therefore more credible. The FDA has made clear that its promotional requirements apply to both forms of marketing:

---

[66] 21 C.F.R. § 99.101(a)(4).
[67] 21 C.F.R. § 202.1(e)(6)(ii).
[68] *See* 21 C.F.R. § 201.56 (providing general requirements for prescription drug labeling); *see also Wyeth v. Levine*, 555 U.S. 555 (2009) (holding that a drug company bears responsibility for the content of its drug labels at all times); 21 C.F.R. § 314.70(c)(6) (iii)(A-C) (allowing manufacturers to make changes that "strengthen . . . a warning, precaution, or adverse reaction" or "strengthen a statement about drug abuse, dependence, psychological effect, or overdosage").

> FDA's regulation of prescription drug product promotion extends both to promotional activities that are carried out by the firm itself, and to promotion conducted on the firm's behalf.
>
> . . . .
>
> Therefore, a firm is responsible for the content generated by its employees or any agents acting on behalf of the firm who promote the firm's product. For example, if an employee or agent of a firm, such as a medical science liaison or paid speaker (e.g., a key opinion leader) acting on the firm's behalf, comments on a third- party site about the firm's product, the firm is responsible for the content its employee or agent provides. A firm is also responsible for the content on a blogger's site if the blogger is acting on behalf of the firm.[69]

213. In addition to being carried out directly or through third parties, drug companies' promotional activity can be branded or unbranded; unbranded marketing refers not to a specific drug, but more generally to a disease state or treatment. By using unbranded communications, drug companies can sidestep the extensive regulatory framework governing branded communications.

214. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements indirectly, through KOLs and Front Groups, and in unbranded marketing materials. These KOLs and Front Groups were important elements of Defendants' marketing plans, which specifically contemplated their use, because they seemed independent and therefore outside FDA oversight. Through unbranded materials, Defendants, with their own knowledge of the risks, benefits and advantages of opioids, presented information and instructions concerning opioids generally that were contrary to, or at best, inconsistent with information and instructions listed on Defendants' branded marketing materials and drug labels. Defendants did so knowing that unbranded materials typically are not submitted to or reviewed by the FDA.

[69] FDA, *Draft Guidance for Industry on Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*, January 2014, at 1, 4, http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm381352.pdf (accessed May 30, 2017).

215. Even where such unbranded messages were channeled through third-party vehicles, Defendants adopted these messages as their own when they cited to, edited, approved, and distributed such materials knowing they were false, misleading, unsubstantiated, unbalanced, and incomplete. Unbranded brochures and other materials that are "disseminated by or on behalf of [the] manufacturer" constitute drug "labeling" that may not be false or misleading in any particular. *See* 21. C.F.R. 202.1(e)(7)(l)(2).[70] Defendants' sales representatives distributed third-party marketing material that was deceptive to Defendants' target audiences. Defendants are responsible for these materials.

216. Moreover, Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Defendants exercised control over their deceptive messages and acted in concert[71] with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

217. For example, drug companies have been admonished for making functional claims in FDA-reviewed branded materials if there is no evidence for such claims. Thus, drug companies were put on notice that the FDA would not allow such claims in branded materials. Defendants instead created and disseminated these same unsupported claims—that opioids allow patients to sleep, return to work, or walk more easily—through *unbranded* marketing materials.

---

[70] This regulation provides: "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and the references published . . . containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling, as defined in section 201(m) of the act." As labeling, such third party-created content distributed by a drug company may not be misleading and must meet the accuracy, substantiation, and fair balance requirements in the FDCA.

[71] As used in this Complaint, the allegation that Defendants "acted in concert" with third parties is intended to mean *both* that they conspired with these third parties to achieve some end and that they aided and abetted these third parties in the commission of acts necessary to achieve it.

218. The third-party publications Defendants assisted in creating and distributing did not include the warnings and instructions mandated by their FDA-required drug labels and consistent with the risks and benefits known to Defendants. For example, these publications either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied that patients faced a serious risk of addiction.

219. By acting through third parties, Defendants were able to both avoid FDA scrutiny and give the false appearance that the messages reflected the views of independent third parties. Later, Defendants would cite to these sources as "independent" corroboration of their own statements. As one physician adviser to Defendants noted, third-party documents not only had greater credibility, but broader distribution as doctors did not "push back" at having materials from, for example, the non-profit American Pain Foundation ("APF") on display in their offices, as they might with first party, drug company pieces. Nevertheless, the independence of these materials was a ruse—Defendants were in close contact with these third parties, paid for and were aware of the misleading information they were disseminating about the use of opioids to treat chronic pain, and regularly helped them to tailor and distribute their misleading, pro-opioid messaging.

220. As part of a strategic marketing scheme, Defendants spread and validated their deceptive messages through the following vehicles: (a) KOLs, who could be counted upon to write favorable journal articles and deliver supportive CMEs; (b) a body of biased and unsupported scientific literature; (c) treatment guidelines; (d) CMEs; (e) unbranded patient education materials; and (f) Front Group patient-advocacy and professional organizations, which exercised their influence both directly and through Defendant-controlled KOLs who served in leadership roles in those organizations.

a. Defendants' Use of KOLs

221. Defendants cultivated a small circle of doctors who, upon information and belief, were selected and sponsored by Defendants solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. In return, these doctors repaid Defendants by touting the benefits of opioids to treat chronic pain.

222. Pro-opioid doctors have been at the hub of Defendants' promotional efforts, presenting the appearance of unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain (even while acknowledging the lack of evidence in support of that position) and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to exert control of each of these modalities through their KOLs.

223. In return, the KOLs' association with Defendants provided not only money, but prestige, recognition, research funding, and avenues to publish. This positioned them to exert even more influence in the medical community.

224. Although some KOLs initially may have advocated for more permissive opioid prescribing with honest intentions, Defendants cultivated and promoted only those KOLs who could be relied on to help broaden the chronic opioid therapy market. Defendants selected, funded, and elevated those doctors whose public positions were unequivocal and supportive of using opioids to treat chronic pain.[72] These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by the drug companies.

[72] Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its effort to persuade the public and regulators that tobacco

225. Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Defendants did not support, acknowledge, or disseminate the publications of doctors critical of the use of chronic opioid therapy. Indeed, one prominent KOL sponsored by Defendants, Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding. Some KOLs have even gone on to become direct employees and executives of Defendants, like Dr. David Haddox, Purdue's Vice President of Risk Management, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

226. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well underway and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

227. Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, typically over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

228. These KOLs were carefully vetted to ensure that they were likely to remain on-message and supportive of a pharmaceutical industry agenda. One measure was a doctor's prior work for trusted Front Groups.

229. Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said—as they did with all their recruited speakers. The KOLs knew, or deliberately ignored, the misleading way in which they

---

was not addictive or dangerous. For example, the tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

portrayed the use of opioids to treat chronic pain to patients and prescribers, but they continued to publish those misstatements to benefit themselves and Defendants, all the while causing harm to County prescribers and patients.

i. *Defendant Russell Portenoy*

230. Defendant Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

231. Defendant Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of APF, an advocacy organization almost entirely funded by Defendants.

232. Defendant Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast in Nassau County and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[73]

233. Defendant Dr. Portenoy has recently admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer

[73] Good Morning America television broadcast, ABC News (Aug. 30, 2010).

than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[74] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[75]

ii. *Defendant Lynn Webster*

234. Another KOL, Defendant Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy.[76] He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

235. Dr. Webster had been under investigation for overprescribing by the DEA, which raided his clinic in 2010. More than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by

[74] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.
[75] *Id.*
[76] Journal supplements are paid for by drug manufacturers and, although they may be designed to blend into the rest of the journal, are not peer-reviewed and constitute drug company advertising.

Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach County doctors.

236. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[77]

b. "Research" That Lacked Supporting Evidence

237. Rather than find a way to actually test the safety and efficacy of opioids for long- term use, Defendants led people to believe that they already had. Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to shape the perceptions of prescribers, patients and payors. This literature was, in fact, marketing material focused on persuading doctors and consumers that the benefits of long-term opioid use outweighed the risks.

238. To accomplish this, Defendants—sometimes through third-party consultants and/or advocacy organizations—commissioned, edited, and arranged for the placement of favorable articles in

[77] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb. 19, 2012).

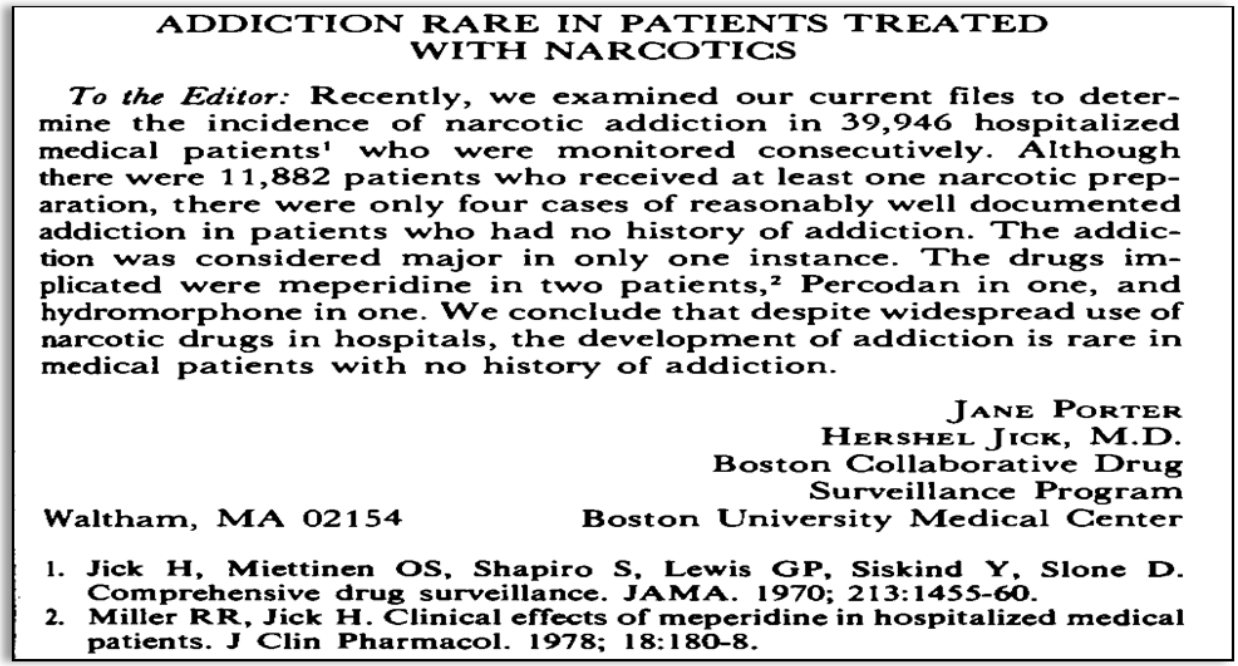
academic journals. Defendants' internal documents reveal plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, that they could use if the pending paper was rejected everywhere else.

239. Defendants coordinated the timing and publication of manuscripts, abstracts, posters/oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. The plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development or any other area that would have specialized knowledge about the drugs and their effects on patients, but in Defendants' marketing departments and with Defendants' marketing and public relations consultants. Defendants often relied on "data on file" or presented posters, neither of which are subject to peer review. They also published their articles not through a competitive process, but in paid journal supplements, which allowed Defendants to publish, in nationally circulated journals, studies supportive of their drugs.

240. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even where references distorted the significance or meaning of the underlying study. Most notably, Purdue promoted a 1980 reference in the well-respected *New England Journal of Medicine*: J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980) ("Porter-Jick Letter"). It is cited 856 times in Google Scholar, and 86 times since 2010. It also appears as a reference in two CME programs in 2012 sponsored by Purdue and Endo.[78] Defendants and those acting on their behalf fail to reveal that this "article" is actually a letter-to-the-editor, not a peer-reviewed study (or any kind of study at all). The Porter-Jick Letter, reproduced in full below, describes a review of the charts of hospitalized patients who had received opioids. (Because it was a

[78] AAPM, Safe Opioid Prescribing Course, February 25-26, 2012, sponsored by Purdue and Endo; "Chronic Pain Management and Opioid Use," October 11, 2012, sponsored by Purdue. Each CME is available for online credit, including to prescribers in Nassau County.

1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.)



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

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

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug Surveillance Program
Waltham, MA 02154 Boston University Medical Center

1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

241. The Porter-Jick Letter notes that, when these patients' records were reviewed, it found almost no references to signs of addiction, though there is no indication that caregivers were instructed to assess or document signs of addiction. None of these serious limitations is disclosed when Defendants, or those acting on their behalf, cite the Porter-Jick Letter, typically as the sole scientific support for the proposition that opioids are rarely addictive, even when taken long-term. In fact, Dr. Jick later complained that his letter had been distorted and misused.

242. Defendants worked not only to create or elevate favorable studies in the literature, but to discredit or bury negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants—often with the help of third-party consultants—targeted a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

243. Defendants' strategies—first, to plant and promote supportive literature and then, to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicts those claims—are in dereliction of their legal obligations. The strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits and superiority of opioids for chronic pain relief resulting in distorted prescribing patterns.

c. Treatment Guidelines

244. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are otherwise not experts, nor trained, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

i. *FSMB*

245. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

246. In 1998, the FSMB developed *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB admitted was produced "in collaboration with pharmaceutical companies."[79] The FSMB Guidelines taught not that opioids could be appropriate in limited cases or after other treatments had failed, but that opioids were "essential" for treatment of

chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose, and they discussed addiction only in the sense that "inadequate understandings" of addiction can lead to "inadequate pain control."

247. A 2004 iteration of the FSMB Guidelines and the 2007 book adapted from the 2004 guidelines, *Responsible Opioid Prescribing*, also make these same claims. These guidelines were posted online and were available to and intended to reach County physicians.

248. The publication of *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors).

249. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards (and through the boards, to practicing doctors), and the FSMB benefitted by earning approximately $250,000 in revenue and commissions from their sale. The FSMB website describes the book as the "leading continuing medication education (CME) activity for prescribers of opioid medications."

250. Drug companies relied on FSMB guidelines to convey the message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors' fear of discipline on its head—doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

251. FSMB, more recently, has moderated its stance. Although the 2012 revision of *Responsible Opioid Prescribing* continued to teach that "pseudoaddiction" is real and that opioid addiction

risk can be managed through risk screening, it no longer recommended chronic opioid therapy as a first choice after the failure of over-the-counter medication and has heightened its addiction and risk warnings.

ii. *AAPM/APS Guidelines*

252. AAPM and the APS are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013 (with AAPM receiving over $2 million).

253. They issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.[80] The co-author of the statement, Dr. Haddox, was, at the time, a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement, which also formed the foundation of the FSMB Guidelines, remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.[81]

254. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[82] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

255. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of

---

[80] Consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, APS & AAPM (1997), *available at* http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf (accessed May 30, 2017).
[81] *Id.*
[82] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain* , 10(2) The Journal of Pain: Official Journal of the American Pain Society 113-130 (2009)

Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Nassau County during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

256. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

iii. *American Geriatrics Society*

257. The American Geriatrics Society ("AGS"), a nonprofit organization serving health care professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[83] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

[83] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1526-4637.2009.00699.x/full (accessed May 30, 2017).

258. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Defendants including Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

259. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[84] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

iv. *Guidelines That Did Not Receive Defendants' Support*

260. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines—the authors of which did not accept drug company funding—reached very different conclusions. The 2012 *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain*, issued by the American Society of Interventional Pain Physicians ("ASIPP"), warned that

[84] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

"[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it." ASIPP's Guidelines further advise that "therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain." ASIPP recommends long-acting opioids in high doses only "in specific circumstances with severe intractable pain" and only when coupled with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[85]

261. Similarly, the 2011 *Guidelines for the Chronic Use of Opioids*, issued by the American College of Occupational and Environmental Medicine, recommend against the "routine use of opioids in the management of patients with chronic pain," finding "at least moderate evidence that harms and costs exceed benefits based on limited evidence," while conceding there may be patients for whom opioid therapy is appropriate.[86]

262. The *Clinical Guidelines on Management of Opioid Therapy for Chronic Pain*, issued by the U.S. Department of Veterans Affairs ("VA") and Department of Defense ("DOD") in 2010, notes that their review:

> revealed the lack of solid evidence based research on the efficacy of long-term opioid therapy. Almost all of the randomized trials of opioids for chronic non-cancer pain

[85] Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).
[86] *American College of Occupational and Environmental Medicine's Guidelines for the Chronic Use of Opioids*, (2011), *available at*: https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf (accessed May 30, 2017).

> were short-term efficacy studies. Critical research gaps . . . include: lack of effectiveness studies on long-term benefits and harms of opioids . . .; insufficient evidence to draw strong conclusions about optimal approaches to risk stratification . . .; lack of evidence on the utility of informed consent and opioid management plans . . .; and treatment of patients with chronic non-cancer pain at higher risk for drug abuse or misuse.[87]

d. Continuing Medical Education

263. CMEs are ongoing professional education programs provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations' conferences, online, or through written publications. Doctors rely on CMEs not only to satisfy licensing requirements, but to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise, they can be especially influential with doctors.

264. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of focus and lack of specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to Defendants' deceptions.

265. In all, Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focused on opioids to the exclusion of alternative treatments, inflated the benefits of opioids, and frequently omitted or downplayed their risks and adverse effects.

[87] Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010), *available at* http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf (accessed May 30, 2017).

266. The American Medical Association ("AMA") has recognized that support from drug companies with a financial interest in the content being promoted "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."[88]

267. Dozens of CMEs that were available to and attended or reviewed by County doctors during the relevant time period did not live up to the AMA's standards.

268. The influence of Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times. Students who read the industry-funded article more frequently noted the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non- industry-funded CME mentioned the risks of death and addiction much more frequently than the other group. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty health care providers have in screening and accounting for source bias.[89]

269. By sponsoring CME programs presented by Front Groups like APF, AAPM, and others, Defendants could expect messages to be favorable to them, as these organizations were otherwise dependent on Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Defendant-

[88] Opinion 9.0115, *Financial Relationships with Industry in CME*, Am. Med. Ass'n (Nov. 2011), *available at* http://eo2.commpartners.com/users/ama/downloads/120328_Opinion_E-9_0115.pdf (accessed May 30, 2017).

[89] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids. Producers of CMEs and Defendants measured the effects of CMEs on prescribers' views on opioids and their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

e. Unbranded Patient Education

270. Pharmaceutical industry marketing experts see patient-focused advertising, including direct-to-consumer marketing, as particularly valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[90] Evidence also demonstrates that physicians are willing to acquiesce to patient demands for a particular drug— even for opioids and for conditions for which they are not generally recommended.[91] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions." Recognizing this fact, Defendants put their relationships with Front Groups to work to engage in largely unbranded patient education about opioid treatment for chronic pain.

271. The drug companies expect that they will recoup their investment in direct-to-consumer advertisements by capturing at least some of any additional prescriptions that result from patients "asking their doctor" about drugs that can treat their pain. Doctors also may review direct-to-consumer materials sales representatives give them to distribute to patients.

f. Defendants' Use of Front Groups

272. As noted above, Defendants Cephalon, Endo, Janssen, and Purdue entered into arrangements with numerous organizations to promote opioids. These organizations depend upon

[90] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 Albany L. Rev. 299, 308 (2013).

[91] Prescribers often accede to patient requests. According to one study, nearly 20% of sciatica patients requesting oxycodone would receive a prescription for it, compared with 1% making no request. More than half of patients requesting a strong opioid received one. J.B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior*, 52(2) Med. Care 294 (2014).

Defendants for significant funding and, in some cases, for their survival. They were involved not only in generating materials and programs for doctors and patients that supported chronic opioid therapy, but also in assisting Defendants' marketing in other ways—for example, responding to negative articles and advocating against regulatory changes that would constrain opioid prescribing. They developed and disseminated pro-opioid treatment guidelines; conducted outreach to groups targeted by Defendants, such as veterans and the elderly; and developed and sponsored CMEs that focused exclusively on use of opioids to treat chronic pain. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages.

273. Several representative examples of such Front Groups are highlighted below, but there are others, too, such as APS, AGS, FSMB, American Chronic Pain Association ("ACPA"), AAPM, American Society of Pain Educators ("ASPE"), NPF, and PPSG.

i. *American Pain Foundation*

274. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half of that funding; Purdue was next, at $1.7 million.

275. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes—including death—among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach County residents.

276. In addition to Perry Fine, Russell Portenoy, and Scott Fishman, who served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

277. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

278. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. As laid out below, APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

279. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications APF could pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

280. APF assisted in other marketing projects for drug companies. One project funded by another drug company—*APF Reporter's Guide: Covering Pain and Its Management* (2008)[92]—recycled text that was originally created as part of the company's training document.

281. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year—this would be a very good issue on which to use some of that. How does that work?"

282. The close relationship between APF and the drug company was not unique, but in fact mirrors the relationships between APF and Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages, support an inference that each Defendant that worked with APF was able to exercise editorial control over its publications.

283. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[93]

[92] https://assets.documentcloud.org/documents/277606/apf-reporters-guide.pdf (accessed May 30, 2017)
[93] http://www.painfoundation.org (last visited May 30, 2017).

ii. *The American Academy of Pain Medicine*

284. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

285. AAPM has received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintains a corporate relations council, whose members pay $25,000 per year (on top of other funding) to participate. The benefits include allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors.

286. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

287. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr.

Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[94]

288. AAPM's staff understood that they and their industry funders were engaged in a common practice. Defendants were able to influence AAPM through both their significant and regular funding, and the leadership of pro-opioid KOLs within the organization.

3. Defendants Acted in Concert with KOLs and Front Groups in the Creation, Promotion, and Control of Unbranded Marketing.

289. Like cigarette manufacturers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively present the risks, benefits, and superiority of opioids to treat chronic pain.

290. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages. These KOLs have worked reciprocally with Defendants to promote misleading messaging regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated to Nassau County prescribers and patients.

291. One vehicle for their collective collaboration was Pain Care Forum ("PCF"). PCF began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and to "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the Forum as "a deliberate

[94] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829 (accessed May 30, 2017).

effort to positively merge the capacities of industry, professional associations, and patient organizations."

292. PCF is comprised of representatives from opioid manufacturers and distributors (including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (*e.g.*, American Academy of Pain Management, APS, and American Society of Pain Educators); patient advocacy groups (*e.g.*, APF and ACPA); and other like-minded organizations (*e.g.*, FSMB and Wisconsin Pain & Policy Studies Group), almost all of which received substantial funding from Defendants.

293. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.[95] This was critical as a REMS that went too far in narrowing the uses or benefits, or highlighting the risks of chronic opioid therapy, would deflate Defendants' marketing efforts. The recommendations—drafted by Will Rowe of APF—claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers."[96] Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, and not undermine, their deceptive marketing of opioids for chronic pain.

[95] The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.
[96] Defendants also agreed that short-acting opioids should also be included in REMS as not to disadvantage the long-acting, branded drugs.

4. Defendants Targeted Vulnerable and Lucrative Populations.

a. The Elderly

294. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression, which, as Defendants acknowledge in their labels (but not in their marketing), occurs more frequently in elderly patients. A 2010 paper in the Archives of Internal Medicine reported that elderly patients who used opioids had a significantly higher rate of death, heart attacks, and strokes than users of NSAIDs. Defendants' targeted marketing to the elderly and the absence of cautionary language in their promotional materials flies in the face of scientific evidence and their own labels, and creates a heightened risk of serious injury to elderly patients.

295. Defendants also promoted the notion—also without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. AGS's 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." Yet, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

296. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

b. Veterans

297. Veterans, too, are suffering greatly from the effects of Defendants' targeted marketing. A 2008 survey showed that prescription drug abuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001. Further, one-third of veterans prescribed opioids as of 2012 remained on take-home opioids for more than 90 days.

Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment. Among former service members receiving VA services nationally in a single year (2005), 1,013 had died of accidental drug overdoses—double the rate of the civilian population.

298. The County has a substantial population of veterans who must cope with the consequences of overprescribing opioids.

299. Opioids are particularly dangerous to veterans. According to a study published in the 2013 Journal of American Medicine, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death. According to a VA Office of Inspector General Report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[97] Again, as with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

300. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury. It notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." The book also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards."

[97] https://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf (accessed May 30, 2017)

As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

301. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[98] It is not the unbiased narrative of a returning war veteran. It is pure marketing, sponsored by Purdue, Endo, and Janssen. Yet, Janssen, for example, supported the marketing effort, and its insufficient disclosures, despite acknowledging on the label for its opioid Duragesic that its use with benzodiazepines "may cause respiratory depression, hypotension, and profound sedation or potentially result in coma." A similar warning is found on the labels of other Defendants' opioids.

302. The deceptive nature of *Exit Wounds* is obvious in comparing it to guidance on opioids published by the VA and DOD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects and death—none of which is disclosed in *Exit Wounds*.

D. Why Defendants' Marketing Messages Are Misleading and Unfair

303. Defendants' marketing of opioids for long-term use to treat chronic pain, both directly and with and through third parties, included information that was false, misleading, contrary to credible scientific evidence and their own labels, and lacked balance and substantiation. Their marketing materials omitted material information about the risks of opioids, and overstated their

[98] FDA guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* FDA Notice, Guidance for Industry, "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs," August 6, 2015.

benefits. Moreover, Defendants inaccurately suggested that chronic opioid therapy was supported by evidence, and failed to disclose the lack of evidence in support of treating chronic pain with opioids.

304. There are seven primary misleading and unfounded representations. Defendants and the third parties with which they teamed:

- misrepresented that opioids improve function;
- concealed the link between long-term use of opioids and addiction;
- misrepresented that addiction risk can be managed;
- masked the signs of addiction by calling them "pseudoaddiction";
- falsely claimed withdrawal is easily managed;
- misrepresented or omitted the greater dangers from higher doses of opioids; and
- deceptively minimized the adverse effects of opioids and overstated the risks of NSAIDs.

305. In addition to these misstatements, Purdue purveyed an eighth deception that OxyContin provides a full 12 hours of pain relief.

306. Exacerbating each of these misrepresentations and deceptions was the collective effort of Defendants and third parties to hide from the medical community the fact that the FDA "is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[99]

1. Defendants and Their Third-Party Allies Misrepresented that Opioids Improve Function

307. Each of the following materials was created with the expectation that, by instructing patients and prescribers that opioids would improve patients' function and quality of life, patients would demand opioids and doctors would prescribe them. These claims also encouraged doctors to

[99] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

continue opioid therapy in the belief that failure to improve pain, function, or quality of life, could be overcome by increasing doses or prescribing supplemental short-acting opioids to take on an as-needed basis for breakthrough pain.

308. However, not only is there no evidence of improvement in long-term functioning, a 2006 study-of-studies found that "[f]or functional outcomes . . . other analgesics were significantly more effective than were opioids."[100] Studies of the use of opioids in chronic conditions for which they are commonly prescribed, such as low back pain, corroborate this conclusion and have failed to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity.[101] Indeed, one Defendant's own internal marketing plans characterized functional improvement claims as "aspirational." Another acknowledged in 2012 that "[s]ignificant investment in clinical data [was] needed" to establish opioids' effect on mitigating quality of life issues, like social isolation.

309. The long-term use of opioids carries a host of serious side effects, including addiction, mental clouding and confusion, sleepiness, hyperalgesia, and immune-system and hormonal dysfunction that degrade, rather than improve, patients' ability to function. Defendants often omitted these adverse effects as well as certain risks of drug interactions from their publications.

310. Yet each of the following statements by Defendants, suggests that the long-term use of opioids improve patients' function and quality of life, and that scientific evidence supports this claim.

---

[100] Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589-1594 (2006). This study revealed that efficacy studies do not typically include data on opioid addiction, such that, if anything, the data overstate effectiveness.

[101] Moreover, users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment (MIDAS), and had higher rates of depression, compared to non-opioid users. They also were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "**most** chronic benign pain patients do have **markedly improved ability to function** when maintained on chronic opioid therapy." (Emphasis added.) b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[102] d. Actavis sales representatives told Nassau County prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life.

[102] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18. 2010), *available at* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

Cephalon	e. Cephalon sponsored the FSMB's Responsible Opioid Prescribing (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. f. Cephalon sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks associated with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The publication is also currently available online. g. Cephalon sponsored a CME written by key opinion leader Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, to December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long- acting opioids. h. Cephalon sales representatives told Nassau County prescribers that opioids would increase patients' ability to function and improve their quality of life.

Endo	i. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. j. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." k. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[103] l. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." m. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. n. Endo sales representatives told Nassau County prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

[103] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. § 202.1(e)(3); *see also* 21 U.S.C. §331(a).

Janssen	o. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved, and its sales force distributed. This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claims that does not exist. The targeting of older adults also ignored heightened opioid risks in this population. p. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. q. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. r. Janssen sales representatives told Nassau County prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work.

Purdue	s. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described as a "54-year- old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively. t. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" had shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online. u. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 annual report. The guide is currently available online. v. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. w. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book. x. Purdue sales representatives told Nassau County prescribers that opioids would increase patients' ability to function and improve their quality of life.

2. Defendants and Their Third-Party Allies Concealed the Truth About the Risk of Addiction from Long-Term Opioid Use

311. The fraudulent representation that opioids are rarely addictive is central to Defendants' scheme. To reach chronic pain patients Defendants, and the Front Groups and KOLs that they directed, assisted, and collaborated with, had to overcome doctors' legitimate fears that opioids would addict their patients. The risk of addiction is an extremely weighty risk—condemning patients to,

among other things, dependence, compulsive use, haziness, a lifetime of battling relapse, and a dramatically heightened risk of serious injury or death. But for Defendants' campaign to convince doctors otherwise, finding benefits from opioid use for common chronic pain conditions sufficient to justify that risk would have, and previously had, posed a nearly insurmountable challenge.

312. Through their well-funded, comprehensive marketing efforts, Defendants and their KOLs and Front Groups were able to change prescriber perceptions despite the well-settled historical understanding and clear evidence that opioids taken long-term are often addictive. Defendants and their third-party partners: (a) brazenly maintained that the risk of addiction for patients who take opioids long-term was low; and (b) omitted the risk of addiction and abuse from the list of adverse outcomes associated with chronic opioid use, even though the frequency and magnitude of the risk—and Defendants' own labels—compelled disclosure.

313. Further, in addition to falsely claiming opioids had low addiction risk or omitting disclosure of the risk of addiction altogether, Defendants employed language that conveyed to prescribers that the drugs had lower potential for abuse and addiction. Further, in addition to making outright misrepresentations about the risk of addiction, or failing to disclose that serious risk at all, Defendants used code words that conveyed to prescribers that their opioid was less prone to abuse and addiction. For instance, sales representatives for Actavis, Endo, Janssen, and Purdue promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger abuse and addiction. Further, Endo actively promoted its reformulated Opana ER on the basis that it was "designed to be crush-resistant," suggesting both (a) that Endo had succeeded in making the drug harder to adulterate, and (b) that it was less addictive, in consequence. In fact, however, Endo knew that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER" and that Opana ER could still be ground and cut into small pieces by those

looking to abuse the drug. In the same vein, Janssen denied that Nucynta ER was an opioid and claimed that it was not addictive, and Purdue claimed that its opioids were not favored by addicts and did not produce a buzz, all of which falsely suggested that its opioids were less likely to be abused or addictive.

314. Each of the following was created with the expectation that, by instructing patients and prescribers that addiction rates are low and that addiction is unlikely when opioids are prescribed for pain, doctors would prescribe opioids to more patients. For example, one publication sponsored exclusively by Purdue—APF's 2011 *A Policymaker's Guide to Understanding Pain & Its Management*—claimed that opioids are not prescribed often enough because of "misconceptions about opioid addiction."[104]

315. Acting directly or with and through third parties, each of the Defendants claimed that the potential for addiction from its drugs was relatively small, or non-existent, even though there was no scientific evidence to support those claims, and the available research contradicted them. A recent literature survey found that while ranges of "problematic use" of opioids ranged from <1% to 81%,[105] abuse averages between 21% and 29% and addiction between 8% and 12%.[106] These estimates are well in line with Purdue's own studies, showing that between 8% and 13% of OxyContin patients became addicted, but on which Purdue chose not to rely, instead citing the Porter-Jick letter.

316. The FDA has found that 20% of opioid patients use two or more pharmacies, 26% obtain opioids from two or more prescribers, and 16.5% seek early refills—all potential "red flags" for

[104] http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (accessed May 30, 2017)
[105] Cited for the low end of that range was the 1980 Porter-Jick letter in the *New England Journal of Medicine*.
[106] Kevin Vowels et al., *Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis*, 156 PAIN 569-76 (April 2015).

abuse or addiction.[107] The FDA in fact has ordered manufacturers of long-acting opioids to "[c]onduct one or more studies to provide quantitative estimates of the serious risks of misuse, abuse, addiction, overdose and death associated with long-term use of opioid analgesics for management of chronic pain," in recognition of the fact that it found "high rates of addiction" in the medical literature.[108]

317. Of course, the significant (and growing) incidence of abuse, misuse, and addiction to opioids is also powerful evidence that Defendants' statements regarding the low risk of addiction were, and are, untrue. This was well-known to Defendants who had access to sales data and reports, adverse event reports, federal abuse and addiction-related surveillance data, and other sources that demonstrated the widening epidemic of opioid abuse and addiction.

318. Acting directly or through and with third parties, each of the Defendants claimed that the potential for addiction even from long-term use of its drugs was relatively small, or non- existent, despite the fact that the contention was false and there was no scientific evidence to support it. Examples of these misrepresentations are laid out below:

[107] Len Paulozzi, M.D., "Abuse of Marketed Analgesics and Its Contribution to the National Problem of Drug Abuse," *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM233244.pdf (accessed May 30, 2017)

[108] September 10, 2013 letter from Bob Rappaport, M.D., to NDA applicants of ER/LA opioid analgesics*, available at* http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf (accessed May 30, 2017).; Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. b. Actavis had a patient education brochure distributed in 2007 that claimed addiction is possible, but it is "less likely if you have never had an addiction problem." Although the term "less likely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. c. Kadian sales representatives told Nassau County prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. d. Kadian sales representatives told Nassau County prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids. e. Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs to County prescribers.

Cephalon	f. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." g. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. h. Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs to County prescribers.

Endo	i. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. j. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was *designed to be crush resistant*, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "post-marketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. k. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that, as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. l. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." m. Endo sponsored CMEs published by APF's NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. n. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." o. Endo distributed a patient education pamphlet edited by key opinion leader Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue.

	p. Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the Pharmacological Management of Persistent Pain in Older Persons. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. q. Endo sales representatives told Nassau County prescribers that its drugs were "steady state," the implications of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. r. Endo provided grants to APF to distribute Exit Wounds (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a concern. s. Endo sales representatives omitted discussion of addiction risks related to Endo's drugs.

Janssen	t. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a concern. The language also implies that as long as a prescription is given, opioid use is not a problem. u. Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

	v. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that [l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a concern. w. Janssen currently runs a website, *Prescriberesponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated." x. A June 2009 Nucynta Training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed." y. Janssen sales representatives told Nassau County prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. z. Janssen sales representatives told Nassau County prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." aa. Janssen sales representatives falsely told prescribers that Duragesic had anti abuse properties when it had none. bb. Janssen's sales representatives told Nassau County prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. cc. Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs.

Purdue	dd. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use.[109] Thus, these misrepresentations wrongly reassure doctors that, as long as they do not observe those signs, they need not be concerned that their patients are abusing or addicted to opioids. ee. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction." ff. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. gg. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[110] The study relied only on the Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a concern. hh. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

[109] Purdue itself submitted briefing materials in October 2010 to a meeting of the FDA's Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee in which it stated that OxyContin was used non-medically by injection 4-17% of the time.

[110] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

	ii. Purdue sponsored APF's *Exit Wounds* (2009), which counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry. jj. Purdue sales representatives told Nassau County prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. kk. Purdue sales representatives told Nassau County prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamper- proof and, after a certain point, patients no longer experience a "buzz" from increased dosage. ll. Advertisements that Purdue sent to Nassau County prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction. mm. Purdue sales representatives omitted discussion of addiction risk related to Purdue's drugs.

319. In addition to denying or minimizing the risk of addiction and abuse generally, Defendants also falsely claimed that their particular drugs were safer, less addictive, and less likely to be abused or diverted than their competitors' or predecessor drugs. In making these claims, Defendants said or implied that because their drug had a "steady-state" and did not produce peaks and valleys, which cause drug-seeking behavior—either to obtain the high or avoid the low—it was less likely to be abused or addicting. Endo also asserted in particular that, because a reformulation of Opana ER was (or was designed to be) abuse-deterrent or tamper-resistant, patients were less likely to become addicted to it. Defendants had no evidence to support any of these claims, which, by FDA regulation, must be based on head-to-head trials;[111] the claims also were false and misleading in that they misrepresented the risks of both the particular drug and opioids as a class.

[111] *See Guidance for Industry*, "Abuse-Deterrent Opioids—Evaluation and Labeling," April 2015 (describing requirements for premarket and postmarket studies).

320. Further, rather than honestly disclose the risk of addiction, Defendants, and the third parties they directed and assisted and whose materials they distributed, attempted to portray those who were concerned about addiction as unfairly denying treatment to needy patients. To increase pressure on doctors to prescribe chronic opioid therapy, Defendants turned the tables; it was doctors who fail to treat their patients' chronic pains with opioids—not doctors who cause their patients to become addicted to opioids—who are failing their patients (and subject to discipline). Defendants and their third-party allies claimed that purportedly overblown worries about addiction cause pain to be under-treated and opioids to be over-regulated and under-prescribed. This mantra of under-treated pain and under-used drugs reinforced Defendants' messages that the risks of addiction and abuse were not significant and were overblown.

321. For example, Janssen's website, *Let's Talk Pain*, warns in a video posted online that "strict regulatory control has made many physicians reluctant to prescribe opioids. The unfortunate casualty in all of this is the patient, who is often undertreated and forced to suffer in silence." The program goes on to say: "Because of the potential for abusive and/or addictive behavior, many healthcare professionals have been reluctant to prescribe opioids for their patients . . . . This prescribing environment is one of many barriers that may contribute to the undertreatment of pain, a serious problem in the United States."

322. In the same vein, a Purdue website called *In the Face of Pain* complains, under the heading of "Protecting Access," that, through at least mid-2013, policy governing the prescribing of opioids was "at odds with" best medical practices by "unduly restricting the amounts that can be prescribed and dispensed"; "restricting access to patients with pain who also have a history of substance abuse"; and "requiring special government-issued prescription forms only for the medications that are capable of relieving pain that is severe." This unsupported and untrue rhetoric

aims to portray doctors who do not prescribe opioids as uncaring, converting their desire to relieve patients' suffering into a mandate to prescribe opioids.

3. Defendants and Their Third-Party Allies Misrepresented that Addiction Risk Can Be Avoided or Managed

323. To this day, defendants each continue to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted. Presumably only to explain why doctors encounter so many patients addicted to opioids, Defendants and their third-party allies have come to admit that some patients could become addicted, but that doctors can avoid or manage that risk by using screening tools or questionnaires. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance abuse, mental illness, or abuse) so that doctors can more closely monitor patients at greater risk of addiction.

324. There are three fundamental flaws in these assurances that doctors can identify and manage the risk of addiction. First, there is no reliable scientific evidence that screening works to accurately predict risk or reduce rates of addiction. Second, there is no reliable scientific evidence that high-risk or addicted patients can take opioids long-term without triggering addiction, even with enhanced monitoring and precautions. Third, there is no reliable scientific evidence that patients without these red flags are necessarily free of addiction risk.

325. Addiction is difficult to predict on a patient-by-patient basis, and there are no reliable, validated tools to do so. A recent Evidence Report by the Agency for Healthcare Research and Quality ("AHRQ"), which "systematically review[ed] the current evidence on long-term opioid therapy for chronic pain" identified "[n]o study" that had "evaluated the effectiveness of risk mitigation strategies, such as use of risk assessment instruments, opioid management plans, patient education, urine drug screening, prescription drug monitoring program data, monitoring instruments, more frequent monitoring intervals, pill counts, or abuse- deterrent formulations on outcomes related to overdose,

addiction, abuse or misuse."[112] Furthermore, attempts to treat high-risk patients, such as those who have a documented predisposition to substance abuse, by resorting to patient contracts, more frequent refills, or urine drug screening are not proven to work in the real world, if busy doctors even in fact attempt them.

326. Most disturbingly, despite the widespread use of screening tools, patients with past substance use disorders—which every tool rates as a risk factor—receive, on average, higher doses of opioids.

327. Each Defendant claimed that the risk of addiction could be avoided or managed, claims that are deceptive and without scientific support:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed."
Endo	c. Endo paid for a 2007 supplement[113] available for continuing education credit in the Journal of Family Practice. This publication, titled Pain Management Dilemmas in Primary Care: Use of Opioids, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain, and advised that patients at high risk of addiction could safely (e.g., without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
Purdue	d. Purdue's unbranded website, In the Face of Pain (inthefaceofpain.com) states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[114]

[112] *The Effectiveness and Risks of Long-term Opioid Treatment of Chronic Pain*, Agency for Healthcare Res. & Quality (September 19, 2014).
[113] The Medical Journal, *The Lancet* found that all of the supplement papers it received failed peer-review. Editorial, "The Perils of Journal and Supplement Publishing," 375 *The Lancet* 9712 (347) 2010.
[114] *See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, Purdue Pharma L.P. (Resources verified Mar. 2012),

	e. Purdue sponsored a 2012 CME program taught by a KOL titled Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior. f. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, titled Managing Patient's Opioid Use: Balancing the Need and Risk. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." g. Purdue sales representatives told Nassau County prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction.

4. Defendants and Their Third-Party Allies Created Confusion By Promoting the Misleading Term "Pseudoaddiction."

328. Defendants and their third-party allies developed and disseminated each of the following misrepresentations with the intent and expectation that, by instructing patients and prescribers that signs of addiction are actually the product of untreated pain, doctors would prescribe opioids to more patients and continue to prescribing them, and patients would continue to use opioids despite signs that the patient was addicted. The concept of "pseudoaddiction" was coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, who consulted for Cephalon, Endo, Janssen, and Purdue. Much of the same language appears in other Defendants' treatment of this issue, highlighting the contrast between "undertreated pain" and "true addiction," as if patients could not experience both. As KOL Dr. Lynn Webster wrote:

www.inthefaceofpain.com/content/uploads/2011/12/factsheet_ProtectingAccess.pdf (accessed May 30, 2017).

"[Pseudoaddiction] obviously became too much of an excuse to give patients more medication.. . . It led us down a path that caused harm. It is already something we are debunking as a concept."[115]

329. Each of the publications and statements below falsely states or suggests that the concept of "pseudoaddiction" is substantiated by scientific evidence and accurately describes the condition of patients who only need, and should be treated with, more opioids:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction."

Cephalon	b. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of "pseudoaddiction." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists.

Endo	c. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing* Pain (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that when faced with signs of aberrant behavior, the doctor should regard it as "pseudoaddiction" and thus, increasing the dose *in most cases . . . should be the clinician's first response*." (emphasis added). d. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction."

Janssen	e. From 2009 to 2011 Janssen's website, *Let's Talk Pain*, stated that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." (emphasis added).

[115] John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, Milwaukee Wisc. J. Sentinel (Feb.19, 2012).

Purdue	f. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described "pseudoaddiction" as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." g. Purdue distributed to physicians, at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including "illicit drug use and deception" it defined as indicative of "pseudoaddiction" or untreated pain. It also states: "Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when *pain is undertreated*. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be *distinguished from true addiction* in that the behaviors resolve when the pain is effectively treated." (Emphasis added.) h. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name, "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." Purdue also spent over $100,000 to support distribution of the book. i. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when *pain is undertreated*. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (Emphasis added.)

5. Defendants and Their Third-Party Allies Claimed Withdrawal is Simply Managed

330. Defendants and their third-party allies promoted the false and misleading messages below with the intent and expectation that, by misrepresenting the difficulty of withdrawing from opioids, prescribers and patients would be more likely to start chronic opioid therapy and would fail to recognize the actual risk of addiction.

331. In an effort to underplay the risk and impact of addiction, Defendants and their third-party allies frequently claim that, while patients become "physically" dependent on opioids, physical dependence can be addressed by gradually tapering patients' doses to avoid the adverse effects of withdrawal. They fail to disclose the extremely difficult and painful effects that patients can experience

when they are removed from opioids—effects that also make it less likely that patients will be able to stop using the drugs.

332. In reality, withdrawal is prevalent in patients after more than a few weeks of therapy. Common symptoms of withdrawal include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, and pain. Some symptoms may persist for months, or even years, after a complete withdrawal from opioids, depending on how long the patient had been using opioids. Withdrawal symptoms trigger a feedback loop that drives patients to seek opioids, contributing to addiction.

333. Each of the publications and statements below falsely states or suggests that withdrawal from opioids was not a problem and they should not be hesitant about prescribing or using opioids:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis's sales representative training claimed opioid withdrawal would take only a week, even in addicted patients.

Endo	b. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days.

Janssen	c. A Janssen PowerPoint presentation used for training its sales representatives titled "Selling Nucynta ER" indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use; Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER. d. Janssen sales representatives told Nassau County prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids.

Purdue	e. Purdue sponsored *APF's A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use. f. Purdue sales representatives told Nassau County prescribers that the effects of withdrawal from opioid use can be successfully managed. g. Purdue sales representatives told Nassau County prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism.

6. Defendants and Their Third-Party Allies Misrepresented that Increased Doses Pose No Significant Additional Risks

334. Each of the following misrepresentations was created with the intent and expectation that, by misrepresenting and failing to disclose the known risks of high dose opioids, prescribers and

patients would be more likely to continue to prescribe and use opioids, even when they were not effective in reducing patients' pain, and not to discontinue opioids even when tolerance required them to reach even higher doses.

335. Defendants and their third-party allies claimed that patients and prescribers could increase doses of opioids indefinitely without added risk, even when pain was not decreasing or when doses had reached levels that were "frighteningly high," suggesting that patients would eventually reach a stable, effective dose. Each of Defendants' claims also omitted warnings of increased adverse effects that occur at higher doses, and misleadingly suggested that there was no greater risk to higher dose opioid therapy.

336. These claims are false. Patients receiving high doses of opioids as part of long-term opioid therapy are three to nine times more likely to suffer an overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The FDA has itself acknowledged that available data suggest a relationship between increased doses and the risk of adverse effects. Moreover, it is harder for patients to terminate use of higher-dose opioids without severe withdrawal effects, which contributes to a cycle of continued use, even when the drugs provide no pain relief and are causing harm—the signs of addiction.

337. Each of the following claims suggests that high-dose opioid therapy is safe:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian.
Cephalon	b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claimed that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. d. Cephalon sales representatives assured Nassau County prescribers that opioids were safe, even at high doses.
Endo	e. Endo sponsored a website, painknowledge.com, through APF and NIPC, which, in 2009, claimed that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurred, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. f. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief."
Janssen	g. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved an its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines and omitted any discussion of risks of increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

Purdue	h. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what—in their view—is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. i. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dose escalations are "sometimes necessary," even indefinitely high ones. This suggested that high dose opioids are safe and appropriate and did not disclose the risks from high dose opioids. This publication is still available online. j. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. k. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. l. Purdue sales representatives told Nassau County prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses.

7. Defendants and Their Third-Party Allies Deceptively Omitted or Minimized Adverse Effects of Opioids and Overstated the Risks of Alternative Forms of Pain Treatment.

338. Each of the following misrepresentations was created with the intent and expectation that, by omitting the known, serious risks of chronic opioid therapy, including the risks of addiction, abuse, overdose, and death, and emphasizing or exaggerating risks of competing products, prescribers and patients would be more likely to choose opioids. Defendants and their third-party allies routinely ignored the risks of chronic opioid therapy. These include (beyond the risks associated with misuse, abuse, and addiction): hyperalgesia, a "known serious risk associated with chronic opioid analgesic

therapy in which the patient becomes more sensitive to certain painful stimuli over time;"[116] hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (disorders frequently coexisting with chronic pain conditions).[117]

339. Despite these serious risks, Defendants asserted, or implied, that opioids were appropriate first-line treatments and safer than alternative treatments, including NSAIDs such as ibuprofen (Advil, Motrin) or naproxen (Aleve). While NSAIDs can pose significant gastrointestinal, renal, and cardiac risks, particularly for elderly patients, Defendants' exaggerated descriptions of those risks were deceptive in themselves, and also made their omissions regarding the risks of opioids all the more striking and misleading. Defendants and their third-party allies described over-the-counter NSAIDs as life-threatening and falsely asserted that they were responsible for 10,000-20,000 deaths annually (more than opioids), when in reality the number is closer to 3,200. This description of NSAIDs starkly contrasted with their representation of opioids, for which the listed risks were nausea, constipation, and sleepiness (but not addiction, overdose, or death). Compared with NSAIDs, opioids are responsible for roughly four times as many fatalities annually.

340. As with the preceding misrepresentations, Defendants' false and misleading claims regarding the comparative risks of NSAIDs and opioids had the effect of shifting the balance of

[116] Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

[117] Several of these risks do appear in the FDA-mandated warnings. *See, e.g.,* the August 13, 2015 OxyContin Label, Section 6.2, identifying adverse reactions including: "abuse, addiction … death, … hyperalgesia, hypogonadism . . . mood altered . . . overdose, palpitations (in the context of withdrawal), seizures, suicidal attempt, suicidal ideation, syndrome of inappropriate antidiuretic hormone secretion, and urticaria [hives]."

opioids' risks and purported benefits. While opioid prescriptions have exploded over the past two decades, the use of NSAIDs has declined during that same time.

341. Each of the following reflects Defendants' deceptive claims and omissions about the risks of opioids, including in comparison to NSAIDs:

Actavis	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, for older persons. c. Kadian sales representatives told Nassau County prescribers that NSAIDs were more toxic than opioids.

Cephalon	d. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. e. Cephalon sales representatives told County prescribers that NSAIDs were more toxic than Cephalon's opioids

Endo	f. Endo distributed a "case study" to prescribers titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. g. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called *"Pain: Opioid Therapy."* This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. h. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. i. Endo sales representatives told Nassau County prescribers that NSAIDs were more toxic than opioids.

Janssen	j. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This publication described the advantages and disadvantages of NSAIDs on one page, and the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "can increase the risk of heart attack and stroke." The only adverse effects of opioids listed are "upset stomach or sleepiness," which the brochure claims will go away, and constipation. k. Janssen sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines. Janssen's label for Duragesic, however, states that use with benzodiazepines "may cause respiratory depression, [low blood pressure], and profound sedation or potentially result in coma. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. l. Janssen sales representatives told Nassau County prescribers that Nucynta was not an opioid, making it a good choice for chronic pain patients who previously were unable to continue opioid therapy due to excessive side effects. This statement was misleading because Nucynta is, in fact, an opioid and has the same effects as other opioids.

Purdue	m. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. n. Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. Treatment Options also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. o. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013; The 2013 version is still available for CME credit. The CME, Overview of Management Options, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. p. Purdue sales representatives told Nassau County prescribers that NSAIDs were more toxic than opioids.

8. Purdue Misleadingly Promoted OxyContin as Providing 12 Hours of Relief

342. In addition to making the deceptive statements above, Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action.

343. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was, upon information and belief, adapted from Purdue's own sales materials:[118]

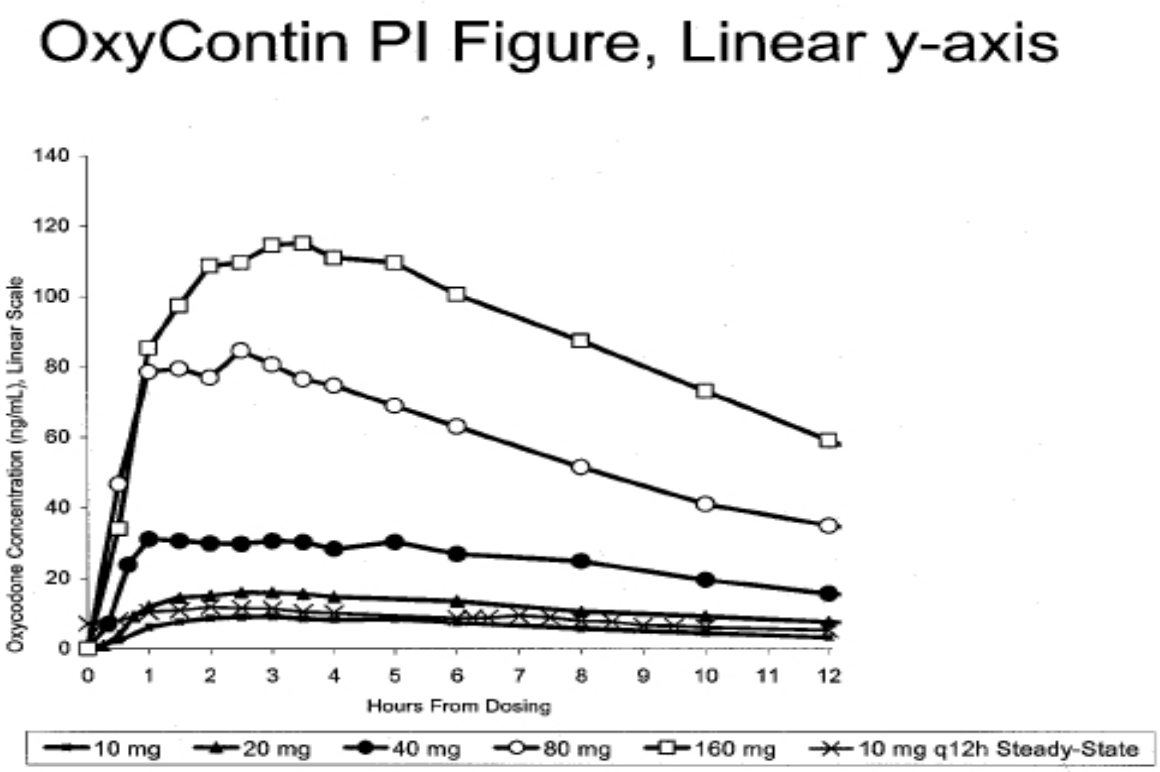


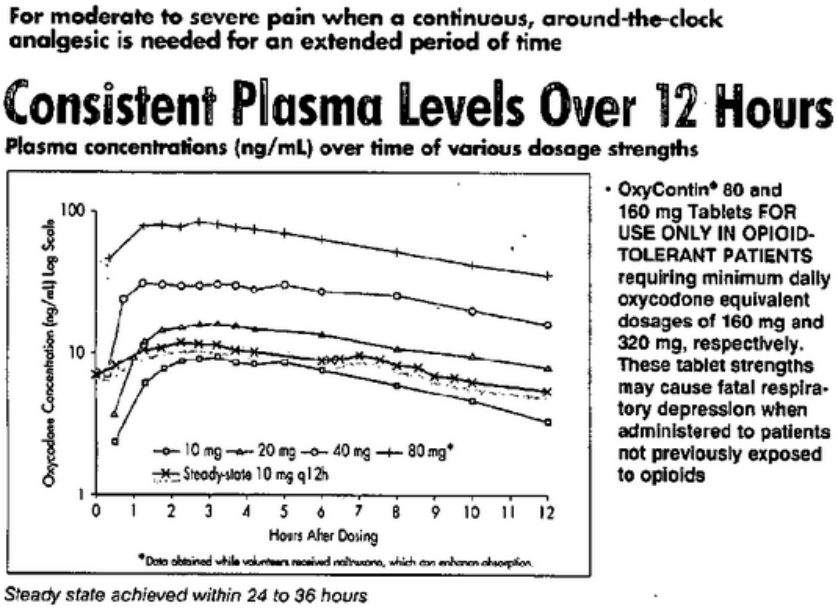
Figure 1

[118] Jim Edwards, "*How Purdue Used Misleading Charts to Hide OxyContin's Addictive Power*," *CBSNews.com*, Sept. 28, 2011, http://www.cbsnews.com/news/how-purdue-used-misleading-charts-to- hide-oxycontins-addictive-power/ *(*accessed May 30, 2017). The 160 mg dose is no longer marketed. Purdue's promotional materials in the past displayed a logarithmic scale, which gave the misleading impression the concentration remained constant.

The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the 12 hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

344. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid—OxyContin is roughly twice as powerful as morphine—triggers a powerful psychological response. OxyContin thus behaves more like an immediate release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full 12 hours and precipitates withdrawal symptoms in patients, a phenomenon known as "end of dose" failure. (The FDA found in 2008 that a "substantial number" of chronic pain patients will experience "end-of-dose failure" with OxyContin.) The combination of fast onset and end-of-dose failure makes OxyContin particularly addictive, even compared with other opioids.

345. Purdue nevertheless has falsely promoted OxyContin as if it were effective for a full 12 hours. Its advertising in 2000 included claims that OxyContin provides "Consistent Plasma Levels Over 12 Hours." That claim was accompanied by a chart depicting plasma levels on a logarithmic scale. The chart minimized the rate of end-of-dose failure by depicting 10 mg in a way that it appeared to be half of 100 mg in the table's y-axis. That chart, shown below, depicts the same information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



346. More recently, other Purdue advertisements also emphasized "Q12h" (meaning twice-daily) dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. Other advertisements that ran in the 2005 and 2006 issues of the *Journal of Pain* depict a sample prescription for OxyContin, with "Q12h" handwritten for emphasis.

347. The information that OxyContin did not provide pain relief for a full 12 hours was known to Purdue, and Purdue's competitors, but was not disclosed to general practitioners. Purdue's knowledge of some pain specialists' tendency to prescribe OxyContin three times per day instead of two (which would have compensated for end-of-dose failure) was set out in Purdue's internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.[119] Even Purdue's competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering "durable" pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-

[119] MEDWATCH refers to the FDA's voluntary adverse event reporting system.

hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to "real" 12-hour dosing.

348. Purdue's failure to disclose the prevalence of end-of-dose failure meant that prescribers in Nassau County were not informed of risks relating to addiction, and that they received the misleading message that OxyContin would be effective for treating chronic pain for the advertised duration. Furthermore, doctors would compensate by increasing the dose or prescribing "rescue" opioids, which had the same effect as increasing the amount of opioids prescribed to a patient.[120, 121]

E. Each Defendant Engaged in Deceptive Marketing, Both Branded and Unbranded, that Targeted and Reached County Prescribers.

349. Defendants—and the Front Groups and KOLs who depended on and worked alongside them—were able to affect a sea change in medical opinion in favor of accepting opioids as a medically necessary long-term treatment for chronic pain. As set forth below, each Defendant contributed to that result through a combination of both direct marketing efforts and third-party marketing efforts over which that Defendant exercised editorial control. These deceptive and misleading statements were directed to, and reached, County prescribers and patients, with the intent of distorting their views on the risks, benefits, and superiority of opioids for treatment of chronic pain.

---

[120] Purdue's *Clinical Issues in Opioid Prescribing*, put out in 2005 under Purdue's unbranded *Partners Against Pain* banner, states that "it is recommended that a supplementary immediate-release medication be provided to treat exacerbations of pain that may occur with stable dosing." References to "rescue" medication appear in publications Purdue sponsored such as APF's *A Policymaker's Guide* (2011) and the 2013 CME *Overview of Pain Management Options*.

[121] The Connecticut Attorney General's office filed a citizens' petition with the FDA on January 27, 2004, requesting that the OxyContin label be amended with a warning not to prescribe the drug more than twice daily as a means of compensating for end-of-dose failure. The FDA denied this request on September 11, 2008. The FDA found that the state had failed to present sufficient evidence that more frequent dosing caused adverse outcomes, but the FDA did not challenge the Connecticut finding that end-of-dose failure of OxyContin was prevalent. Indeed, the FDA found that end-of-dose failure affected a "substantial" number of chronic pain patients prescribed OxyContin.

350. Defendants engaged in their deceptive marketing campaign, both nationwide and in Nassau County, using a number of strategies. Defendants trained their sales forces and recruited physician speakers to deliver these deceptive messages and omissions, and they in turn conveyed them to prescribers. Defendants also broadly disseminated promotional messages and materials, both by delivering them personally to doctors during detailing visits and by mailing deceptive advertisements directly to prescribers. Because they are disseminated by Defendant drug manufacturers and relate to Defendants' drugs, these materials are considered "labeling" within the meaning of 21 C.F.R. § 1.3(a), which means Defendants are liable for their content.

351. As described below, the County has located a number of County-area prescribers who received Defendants' misrepresentations. Each of the misrepresentations received by these doctors constitutes an integral piece of a centrally directed marketing strategy to change medical perceptions regarding the use of opioids to treat chronic pain. Defendants were aware of each of these misrepresentations, and Defendants approved of them and oversaw their dissemination at the national, corporate level.

1. Acatvis

352. As described below, Actavis promoted its branded opioid, Kadian, through a highly deceptive marketing campaign, carried out principally through its sales force and recruited physician speakers. As internal documents indicate, this campaign rested on a series of misrepresentations and omissions regarding the risks, benefits, and superiority of opioids, and indeed incorporated each of the types of deceptive messages. Based on the highly coordinated and uniform nature of Actavis's marketing, Actavis conveyed these deceptive messages to County prescribers. Actavis did so with the

intent that County prescribers and/or consumers would rely on the messages in choosing to use opioids to treat chronic pain.[122]

a. Actavis' Deceptive Direct Marketing

353. To help devise its marketing strategy for Kadian, Actavis commissioned a report from one of its consultants in January 2005 about barriers to market entry. The report concluded that two major challenges facing opioid manufacturers in 2005 were (i) overcoming "concerns regarding the safety and tolerability" of opioids, and (ii) the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior." To address these challenges, the report advocated a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience" with an "emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience." This would entail the creation of "effective copy points . . . backed by published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect profile." According to the report, this would allow physicians to "reach[] a mental agreement" and change their "practice behavior" without having first evaluated supporting data—of which Actavis (and other Defendants) had none.

354. The consulting firm predicted that this manufactured body of literature "w[ould], in turn, provide greater support for the promotional message and add credibility to the brand's advocates" based on "either actual or ***perceived*** 'scientific exchange'" in relevant medical literature. (emphasis added). To this end, it planned for three manuscripts to be written during the first quarter of 2005. Of these, "[t]he neuropathic pain manuscript will provide evidence demonstrating KADIAN is as effective in patients with presumptive neuropathic pain as it is in those with other pain types"; "[t]he elderly subanalysis . . . will provide clinicians with evidence that KADIAN is efficacious and well

[122] Actavis also sold various generic opioids, including Norco, which were widely prescribed in Nassau County and benefited from Actavis's overall promotion of opioids, but were not directly marketed by sales representatives.

tolerated in appropriately selected elderly patients" and will "be targeted to readers in the geriatrics specialty"; and "[t]he QDF/BID manuscript will . . . .call attention to the fact that KADIAN is the only sustained-release opioid to be labeled for [once or twice daily] use." In short, Actavis knew exactly what each study would show—and how that study would fit into its marketing plan—before it was published. Articles matching Actavis's descriptions later appeared in the *Journal of Pain* and the *Journal of the American Geriatrics Society*.

355. To ensure that messages based on this science reached individual physicians, Actavis deployed sales representatives, or detailers, to visit prescribers in Nassau County and across the country. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing.

356. To track its detailers' progress, Actavis's sales and marketing department actively monitored the prescribing behavior of physicians. It tracked the Kadian prescribing activity of individual physicians, and assessed the success of its marketing efforts by tabulating how many Kadian prescriptions a prescriber wrote after he or she had been detailed. As described below, Kadian monitored numerous County physicians.

357. Actavis also planned to promote Kadian by giving presentations at conferences of organizations where it believed it could reach a high concentration of pain specialists. Its choice of conferences was also influenced by the host's past support of opioids. For example, Actavis documents show that Actavis presented papers concerning Kadian at an annual meeting of AGS because AGS's guidelines "support the use of opioids."

358. Actavis targeted prescribers using both its sales force and recruited physician speakers, as described below.

i. *Actavis' Deceptive Sales Training*

359. Actavis's sales representatives targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in delivering Actavis's marketing strategies and talking points to individual prescribers.

360. Actavis's strategy and pattern of deceptive marketing is evident in its internal training materials. A sales education module titled "Kadian Learning System" trained Actavis's sales representatives on the marketing messages—including deceptive claims about improved function, the risk of addiction, the false scientific concept of "pseudoaddiction," and opioid withdrawal—that sales representatives were directed and required, in turn, to pass on to prescribers, nationally and in Nassau County.

361. The sales training module, dated July 1, 2010, includes the misrepresentations documented in this Complaint, starting with its promise of improved function. The sales training instructed Actavis sales representatives that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy," when, in reality, available data demonstrate that patients on chronic opioid therapy are *less likely* to participate in daily activities like work. The sales training also misleadingly implied that the dose of prescription opioids could be escalated without consequence and omitted important facts about the increased risks of high dose opioids. First, Actavis taught its sales representatives, who would pass the message on to doctors, that pain patients would not develop tolerance to opioids, which would have required them to receive increasing doses: "Although tolerance and dependence do occur with long-term use of opioids, many studies have shown that tolerance is limited in most patients with [Chronic pain]." Second, Actavis instructed its sales personnel that opioid "[d]oses are titrated to pain relief, and so no ceiling dose can be given as to the recommended maximal dose." Actavis failed to explain to its sales representatives and, through them, to doctors, the greater risks associated with opioids at high doses.

362. Further, the 2010 sales training module highlighted the risks of alternate pain medications without providing a comparable discussion of the risks of opioids, painting the erroneous and misleading impression that opioids are safer. Specifically, the document claimed that "NSAIDs prolong the bleeding time by inhibiting blood platelets, which can contribute to bleeding complications" and "can have toxic effects on the kidney." Accordingly, Actavis coached its sales representatives that "[t]he potential toxicity of NSAIDs limits their dose and, to some extent, the duration of therapy" since "[t]hey should only be taken short term." By contrast, the corresponding section related to opioids neglects to include a *single* side effect or risk associated with the use of opioids, including from long-term use.

363. This sales training module also severely downplayed the main risk associated with Kadian and other opioids—addiction. It represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." This falsely suggests that few patients would become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors could screen for those patients and safely prescribe to others. To the contrary, opioid addiction affects a significant population of patients; while patients with a history of abuse may be more prone to addiction, all patients are at risk, and doctors may not be able to identify, or safely prescribe to, patients at greater risk.

364. The sales training also noted that there were various "signs associated with substance abuse," including past history or family history of substance or alcohol abuse, frequent requests to change medication because of side effects or lack of efficacy, and a "social history of dysfunctional or high-risk behaviors including multiple arrests, multiple marriages, abusive relationships, etc." This is

misleading, as noted above, because it implies that only patients with these kinds of behaviors and history become addicted to opioids.

365. Further, the sales training neglected to disclose that no risk-screening tools related to opioids have ever been scientifically validated. The AHRQ recently issued an Evidence Report that could identify "[n]o study" that had evaluated the effectiveness of various risk mitigation strategies—including the types of patient screening implied in Actavis's sales training—on outcomes related to overdose, addiction, abuse or misuse.

366. The sales training module also directed representatives to counsel doctors to be on the lookout for the signs of "[p]seudoaddiction," which were defined as "[b]ehaviors (that mimic addictive behaviors) exhibited by patients with inadequately treated pain." However, the concept of "pseudoaddiction" is unsubstantiated and meant to mislead doctors and patients about the risks and signs of addiction.

367. Finally, the 2010 national training materials trivialized the harms associated with opioid withdrawal by explaining that "[p]hysical dependence simply requires a tapered withdrawal should the opioid medication no longer be needed." This, however, overlooks the fact that the side effects associated with opiate withdrawal are severe and a serious concern for *any person* who wishes to discontinue long-term opioid therapy.

368. The Kadian Learning System module dates from July 2010, but Actavis sales representatives were passing deceptive messages on to prescribers even before then. A July 2010 "Dear Doctor" letter issued by the FDA indicated that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]." Certain risks that were misrepresented included the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid agonists have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject

to criminal diversion." The FDA also took issue with an advertisement for misrepresenting Kadian's ability to help patients "live with less pain and get adequate rest with less medication," when the supporting study did not represent "substantial evidence or substantial clinical experience."

369. Actavis's documents also indicate that the company continued to deceptively market its drugs after 2010. Specifically, a September 2012 Kadian Marketing Update, and the "HCP Detail" aid contained therein, noted that Kadian's "steady state plasma levels" ensured that Kadian "produced higher trough concentrations and a smaller degree of peak-to-trough fluctuations" than other opioids.

370. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the "steady-state" message. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were influenced by Actavis's messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and wouldn't "be posing high risk for addiction." As a result, Actavis's marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential".

371. Finally, the internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines with doctors during detailing visits. These guidelines deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories.

ii. *Actavis' Deceptive Speaking Training*

372. Actavis also increasingly relied on speakers—physicians whom Actavis recruited to market opioids to their peers—to convey similar marketing messages. Actavis set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. Actavis sales representatives, who were required

to make a certain number of sales visits each day and week, saw the definition of sales call expanded to accommodate these changes; such calls now included physicians' "breakfast & lunch meetings with Kadian advocate/speaker."

373. A training program for Actavis speakers included training on many of the same messages found in the Kadian Learning System, as described below. The deceptive messages in Actavis's speakers' training are concerning for two reasons: (a) the doctors who participated in the training were, themselves, prescribing doctors, and the training was meant to increase their prescriptions of Kadian; and (b) these doctors were trained, paid, and directed to deliver these messages to other doctors who would write prescriptions of Kadian.

374. Consistent with the training for sales representatives, Actavis's speakers' training falsely minimized the risk of addiction posed by long-term opioid use. Actavis claimed, without scientific foundation, that "[o]pioids can be used with minimal risk in chronic pain patients without a history of abuse or addiction." The training also deceptively touted the effectiveness of "Risk Tools," such as the Opioid Risk Tool, in determining the "risk for developing aberrant behaviors" in patients being considered for chronic opioid therapy. In recommending the use of these screening tools, the speakers' training neglected to disclose that none of them had been scientifically validated.

375. The speakers' training also made reference to "pseudoaddiction" as a "[c]ondition characterized by behaviors, such as drug hoarding, that outwardly mimic addiction but are in fact driven by a desire for pain relief and usually signal undertreated pain." It then purported to assist doctors in identifying those behaviors that *actually* indicated a risk of addiction from those that did not. Behaviors it identified as "[m]ore suggestive of addiction" included "[p]rescription forgery," "[i]njecting oral formulations," and "[m]ultiple dose escalations or other nonadherence with therapy despite warnings." Identified as "[l]ess suggestive of addiction" were "[a]ggressive complaining about the need for more drugs," "[r]equesting specific drugs," "[d]rug hoarding during periods of reduced

symptoms," and "[u]napproved use of the drug to treat another symptom." By portraying the risks in this manner, the speakers' training presentation deceptively gave doctors a false sense of security regarding the types of patients who can become addicted to opioids and the types of behaviors these patients exhibit.

376. The speakers' training downplayed the risks of opioids, while focusing on the risks of competing analgesics like NSAIDs. For example, it asserted that "Acetaminophen toxicity is a major health concern." The slide further warned that "Acetaminophen poisoning is the most common cause of acute liver failure in an evaluation of 662 US Subjects with acute liver failure between 1998-2003," and was titled "Opioids can be a safer option than other analgesics." However, in presenting the risks associated with opioids, the speakers' training focused on nausea, constipation, and sleepiness, and ignored the serious risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness; increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines. As a result, the training exaggerated the risks of NSAIDs, both absolutely and relative to opioids, to make opioids appear to be a more attractive first-line treatment for chronic pain.

377. The speakers' training also misrepresented the risks associated with increased doses of opioids. For example, speakers were instructed to "[s]tart low and titrate until patient reports adequate analgesia" and to "[s]et dose levels on [the] basis of patient need, not on predetermined maximal dose." However, the speakers' training neglected to warn speakers (and speakers bureau attendees) that patients on high doses of opioids are more likely to suffer adverse events.

b. Actavis's Deceptive Statements to Nassau County Prescribers and Patients

378. The misleading messages and training materials Actavis provided to its sales force and speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This

deception was national in scope and included Nassau County. Actavis's nationwide messages reached Nassau County prescribers in a number of ways. For example, they were carried into Nassau County by Actavis's sales representatives during detailing visits as well as made available to County patients and prescribers through websites and ads, including ads in prominent medical journals. They have also been delivered to County prescribers by Actavis's paid speakers, who were required by Actavis policy and by FDA regulations to stay true to Actavis's nationwide messaging.

379. Once trained, Actavis's sales representatives and speakers were directed to, and did, visit potential prescribers in Nassau County, as elsewhere, to deliver their deceptive messages. These contacts are demonstrated by Actavis's substantial effort in tracking the habits of individual County physicians prescribing Kadian, and by the direct evidence of Actavis detailing County prescribers.

380. Actavis tracked, in substantial detail, the prescribing behavior of Nassau County area physicians.

2. Cephalon

381. At the heart of Cephalon's deceptive promotional efforts was a concerted and sustained effort to expand the market for its branded opioids, Actiq and Fentora, far beyond their FDA-approved use in opioid-tolerant cancer patients. Trading on their rapid-onset formulation, Cephalon touted its opioids as the answer to "breakthrough pain"—a term its own KOL allies planted in the medical literature—whether cancer pain or not. Cephalon promoted this message through its sales force, paid physician speakers, advertisements, and CMEs, even after the FDA issued the company warnings and rejected an expanded drug indication.

382. Even as it promoted Actiq and Fentora off-label, Cephalon also purveyed many of the deceptive messages described above. It did so both directly—through detailing visits and speaker programs—and through the publications and CMEs of its third-party partners. These messages

included misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids.

383. Based on the highly coordinated and uniform nature of Cephalon's marketing, Cephalon conveyed these deceptive messages to Nassau County prescribers. The materials that Cephalon generated in collaboration with third-parties were also distributed or made available in Nassau County. Cephalon distributed these messages, or facilitated their distribution, in Nassau County with the intent that Nassau County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Cephalon's Deceptive Direct Marketing

384. Like the other Defendants, Cephalon directly engaged in misleading and deceptive marketing of its opioids through its sales force and branded advertisements. These messages were centrally formulated and intended to reach prescribers nationwide, including those practicing in the Nassau County area. Cephalon also spent the money necessary to aggressively promote its opioid drugs, setting aside $20 million to market Fentora in 2009 alone.

i. *Cephalon's Fraudulent Off-Label Marketing of Actiq and Fentora*

385. Chief among Cephalon's direct marketing efforts was its campaign to deceptively promote its opioids for off-label uses. Cephalon reaps significant revenue from selling its opioids for treatment of chronic non-cancer pain. However, neither of its two opioid drugs— Actiq or Fentora— is approved for this purpose. Instead, both have indications that are very clearly and narrowly defined to limit their use to a particular form of cancer pain. Despite this restriction, and in order to claim its piece of the broader chronic non-cancer pain market, Cephalon deceptively and unlawfully marketed Actiq and then Fentora for patients and uses for which they were not safe, effective, or allowed. This resulted in prescriptions written and paid and, grievously, caused patients to be injured and die.

Cephalon's efforts to expand the market for its drugs beyond cancer pain extended to Nassau County prescribers.

a) Cephalon launched its fraudulent marketing scheme for Actiq

386. Cephalon's Actiq is a powerful opioid narcotic that is delivered to the bloodstream by a lollipop lozenge that dissolves slowly in the mouth. As described by one patient, Actiq "tastes like the most delicious candy you ever ate."[123]

387. Actiq is appropriately used only to treat "breakthrough" cancer pain that cannot be controlled by other medications. Breakthrough pain is a short-term flare of moderate-to- severe pain in patients with otherwise stable persistent pain. Actiq is a rapid-onset drug that takes effect within 10-15 minutes but lasts only a short time. It is also an extremely strong drug, considered to be at least 80 times more powerful than morphine. Fentanyl, a key ingredient in Actiq, has been linked to fatal respiratory complications in patients. Actiq is not safe in any dose for patients who are not opioid tolerant, meaning patients who have taken specific doses of opioids for a week or longer and whose systems have acclimated to the drugs.

388. In 1998, the FDA approved Actiq "***ONLY*** for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[124] (emphasis in FDA document). Because of Actiq's dangers, wider, off-label uses—as the FDA label makes clear—are not permitted:

> This product ***must not*** be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, ACTIQ is contraindicated in the management of acute or postoperative pain.[125]

---

[123] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J., Nov. 3, 2006.
[124] FDA Approval Letter for NDA 20-747 (Nov. 4, 1998) at 5, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf (accessed May 30, 2017)
[125] Actiq Drug Label, July 2011. The 1998 version does not substantively differ: "Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, *Actiq* is

389. Actiq and Fentora are thus intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain. Unlike other drugs, of which off-label uses are permitted but cannot be promoted by the drug maker, Actiq and Fentora are so potent that off- label use for opioid naïve patients is barred by the FDA, as their labels make clear.

390. Notwithstanding the drug's extreme potency and related dangers, and the FDA's explicit limitations, Cephalon actively promoted Actiq for chronic non-cancer pain—an unapproved, off-label use. Cephalon marketed Actiq as appropriate for the treatment of various conditions including back pain, headaches, pain associated with sports-related injuries, and other conditions not associated with cancer and for which it was not approved, appropriate, or safe.

391. Actiq's initial sales counted in the tens of millions of dollars, corresponding to its limited patient population. But by 2005, Actiq sales reached $412 million, making it Cephalon's second-highest selling drug. As a result of Cephalon's deceptive, unlawful marketing, sales exceeded $500 million by 2006.

b) October 1, 2006 – Cephalon fraudulently marked Actiq's successor drug, Fentora

392. Actiq was set to lose its patent protection in September 2006. To replace the revenue stream that would be lost once generic competitors came to market, Cephalon purchased a new opioid drug, Fentora, from Cima Labs and, in August 2005, submitted a New Drug Application ("NDA") to the FDA for approval. Like Actiq, Fentora is an extremely powerful and rapid-onset opioid. It is administered by placing a tablet in the mouth until it disintegrates and is absorbed by the mucous membrane that lines the inside of the mouth.

---

contra- indicated in the management of acute or postoperative pain. This product **must not** be used in opioid non-tolerant patients." (emphasis in original).

393. On September 25, 2006, the FDA approved Fentora, like Actiq, only for the treatment of breakthrough cancer pain in cancer patients who were already tolerant to around- the-clock opioid therapy for their underlying persistent cancer pain. Fentora's unusually strong and detailed black box warning label—the most serious medication warning required by the FDA—makes clear that, among other things:

> Fatal respiratory depression has occurred in patients treated with FENTORA, including following use in opioid non-tolerant patients and improper dosing. The substitution of FENTORA for any other fentanyl product may result in fatal overdose.
>
> Due to the risk of respiratory depression, FENTORA is contraindicated in the management of acute or postoperative pain including headache/migraine and in opioid non-tolerant patients.[126]

394. When Cephalon launched Fentora on October 1, 2006, it picked up the playbook it had developed for Actiq and simply substituted in Fentora. Cephalon immediately shifted 100 general pain sales representatives from selling Actiq to selling Fentora to the very same physicians for uses that would necessarily and predictably be off-label. Cephalon's marketing of Actiq therefore "primed the market" for Fentora. Cephalon had trained numerous KOLs to lead promotional programs for Fentora, typically including off-label uses for the drug. Cephalon billed Fentora as a major advance that offered a significant upgrade in the treatment of breakthrough pain generally—not breakthrough cancer pain in particular—from Actiq. Cephalon also developed a plan in 2007 to target elderly chronic pain patients via a multi-city tour with stops at AARP events, YMCAs, and senior living facilities.

395. On February 12, 2007, only four months after the launch, Cephalon CEO Frank Baldino told investors:

> [W]e've been extremely pleased to retain a substantial portion, roughly 75% of the ` rapid onset opioid market. We executed our transition strategy and the results in

[126] Fentora Drug Label, February 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021947s008lbl.pdf (accessed May 30, 2017)

> our pain franchise have been better than we expected. With the successful launch of FENTORA and the progress in label expansion program, we are well positioned to grow our pain franchise for many years to come.[127]

396. On May 1, 2007, just seven months after Fentora's launch, Cephalon's then-Executive Vice President for Worldwide Operations, Bob Roche, bragged to financial analysts that Fentora's reach would exceed even Actiq's. He described the company's successful and "aggressive" launch of Fentora that was persuading physicians to prescribe Fentora for ever broader uses. He identified two "major opportunities"—treating breakthrough cancer pain and:

> The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain. . . .
> . . . .
> We believe that a huge opportunity still exists as physicians and patients recognize FENTORA as their first choice rapid onset opioid medication. . . . [opioids are] widely used in the treatment of. . . non-cancer patients . . . .
> . . . .
> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and wellbeing and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[128]

---

[127] *See Cephalon Q4 2006 Earnings Call Transcript,* Seeking Alpha (February 12, 2007, 8:48 PM EST) at 5, http://seekingalpha.com/article/26813-cephalon-q4-2006-earnings-call-transcript (accessed May 30, 2017)

[128] *See Cephalon Q1 2007 Earnings Call Transcript,* Seeking Alpha (May 1, 2007, 8:48 PM EST) at 23,

c) September 2007 – Reports of death and serious side effects led the FDA to issue a public health warning for Fentora

397. On September 10, 2007, Cephalon sent letters to doctors warning of deaths and other "serious adverse events" connected with the use of Fentora, indicating that "[t]hese deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution."[129] The warning did not mention Cephalon's deliberate role in the "improper patient selection."

398. Two weeks later, the FDA issued its own Public Health Advisory. The FDA emphasized, once again, that Fentora should be prescribed only for approved conditions and that dose guidelines should be carefully followed. The FDA Advisory made clear that several Fentora-related deaths had occurred in patients who were prescribed the drug for off-label uses. The FDA Advisory warned that Fentora should not be used for any off-label conditions, including migraines, post-operative pain, or pain due to injury, and that it should be given only to patients who have developed opioid tolerance. The Advisory reiterated that, because Fentora contains a much greater amount of fentanyl than other opiate painkillers, it is not a suitable substitute for other painkillers.[130]

399. Notwithstanding the regulatory scrutiny, Cephalon's off-label marketing continued. Cephalon's 2008 internal audit of its Sales & Marketing Compliance Programs concluded that marketing and tactical documents, as written, may be construed to promote off-label uses. The same report acknowledged that Cephalon lacked a process to confirm that speakers' program participants

---

http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript?page=1 (accessed May 30, 2017)

[129] Letter from Jeffrey M. Dayno, M.D., Vice President, Medical Services, Cephalon, Inc. to Healthcare Providers (Sept. 10, 2007), http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMed icalProducts/UCM154439.pdf (accessed May 30, 2017).

[130] FDA Public Health Advisory, *Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm (accessed May 30, 2017)

were following Cephalon's written, formal policies prohibiting off-label promotion, and that "non-compliant [Cephalon Speaker Programs] may be taking place." Moreover, the report acknowledged that Cephalon's "call universe" may include "inappropriate prescribers"— prescribers who had nothing to do with cancer pain.

d) May 6, 2008 – The FDA rejected Cephalon's request for expanded approval of Fentora

400. Cephalon filed a supplemental new drug application, ("sNDA"), asking the FDA to approve Fentora for the treatment of non-cancer breakthrough pain. Cephalon admitted that Fentora already had been heavily prescribed for non-cancer pain, but argued that such widespread use demonstrated why Fentora should be approved for these wider uses.[131] Cephalon's application also conceded that "[t]o date, no medication has been systematically evaluated in clinical studies or approved by the FDA for the management of [breakthrough pain] in patients with chronic persistent non-cancer-related pain." *Id.*

401. In response to Cephalon's application, the FDA presented data showing that 95% of all Fentora use was for treatment of non-cancer pain.[132] By a vote of 17-3, the relevant Advisory Committee—a panel of outside experts—voted against recommending approval of Cephalon's sNDA for Fentora, citing the potential harm from broader use. On September 15, 2008, the FDA denied Cephalon's application and requested, in light of Fentora's already off- label use, that Cephalon implement and demonstrate the effectiveness of proposed enhancements to Fentora's Risk

[131] *See Fentora CII: Advisory Committee Briefing Document,* U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4356b2-02-Cephalon.pdf (accessed May 30, 2017)

[132] *See* Yoo Jung Chang & Lauren Lee, *Review of Fentora and Actiq Adverse Events from the Adverse Event Reporting System ("AERS") Database*, U.S. FDA Anesthetic & Life Support Drugs Advisory Comm. & Drug Safety & Risk Mgmt. Advisory Comm. (May 6, 2008), http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-02-FDAcorepresentations.ppt#289,1 (accessed May 30, 2017).

Management Program. In December 2008, the FDA followed that request with a formal request directing Cephalon to submit a Risk Evaluation and Mitigation Strategy for Fentora.

e) March 26, 2009 – the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") warned Cephalon about its misleading advertising of Fentora

402. Undeterred by the rejection of its sNDA, Cephalon continued to use its general pain sales force to promote Fentora off-label to pain specialists as an upgrade of Actiq for the treatment of non-cancer breakthrough pain. Deceptively and especially dangerously, Cephalon also continued to promote Fentora for use by all cancer patients suffering breakthrough cancer pain, and not only those who were opioid tolerant.

403. On March 26, 2009, DDMAC issued a Warning Letter to Cephalon, telling Cephalon that its promotional materials for Fentora amounted to deceptive, off-label promotion of the drug.[133] Specifically, the Warning Letter asserted that a sponsored link on Google and other search engines for Fentora, which said "[l]earn about treating breakthrough pain in patients with cancer,"[134] was improper because it "misleadingly broaden[ed] the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora therapy . . . when this is not the case."

404. DDMAC emphasized that Fentora's label was limited to cancer patients with breakthrough pain **"*who are already receiving and who are tolerant to around-the-clock opioid***

[133] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (March 26, 2009), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166238.pdf (accessed May 30, 2017).

[134] Screen shots of the sponsored link are available here: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM166240.pdf (accessed May 30, 2017).

***therapy for their underlying persistent cancer pain.*"** (emphasis in original). DDMAC explained that the advertisement was "especially concerning given that Fentora **must not** be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids." (Emphasis in original). DDMAC also warned Cephalon that, based on a review of Cephalon-sponsored links for Fentora on internet search engines, the company's advertisements were "misleading because they make representations and/or suggestions about the efficacy of Fentora, but fail to communicate **any** risk information associated with the use" of the drug. (emphasis in original).

f) Cephalon continues to knowingly, deceptively, and illegally promote Fenotra for off-label uses

405. Cephalon's own market research studies confirm that its Fentora promotions were not focused on physicians who treat breakthrough cancer pain. Cephalon commissioned several market research studies to determine whether oncologists provided an "adequate" market potential for Fentora. These studies' central goal was to determine whether oncologists treat breakthrough cancer pain themselves, or whether they refer such patients to general pain specialists. The first study, completed in 2007, reported that 90% of oncologists diagnose and treat breakthrough cancer pain themselves, and do not refer their breakthrough cancer pain patients to pain specialists. The second study, completed in 2009, confirmed the results of the 2007 study, this time reporting that 88% of oncologists diagnose and treat breakthrough cancer pain themselves and rarely, if ever, refer those patients to general pain specialists. (One reason that general pain specialists typically do not treat oncological pain is that the presence of pain can, in itself, be an indicator of a change in the patient's underlying condition that should be monitored by the treating oncologist.)

406. Cephalon was well aware that physicians were prescribing Fentora for off-label uses.

407. Cephalon was also aware that its detailing had an impact on prescription rates.

408. In 2011, Cephalon wrote and copyrighted an article titled "2011 Special Report: An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®)" that was published in *Pain Medicine News*.[135] The article promoted Cephalon's drugs for off-label uses by stating that the "judicious use of opioids can facilitate effective and safe management of chronic pain" and noted that Fentora "has been shown to be effective in treatment of [break through pain] associated with multiple causes of pain," not just cancer.[136]

ii. *Cephalon's Misrepresentation of the Risks Associated with the Use of Opioids for the Long-Term Treatment of Chronic Pain*

409. Cephalon's conduct in marketing Actiq and Fentora for chronic non-cancer pain, despite their clear (and deadly) risks and unproved benefits, was an extension, and reaped the benefits, of Cephalon's generally deceptive promotion of opioids for chronic pain.

410. There is insufficient scientific evidence to corroborate a link between chronic opioid therapy and increased functionality. There is however, sufficient evidence to show increased risks of overdose and addiction .[137]

411. Along with deploying its sales representatives, Cephalon used speakers bureaus to help reach prescribers. The company viewed each treating physician as a vehicle to generate prescriptions – whether written by that physician directly or caused indirectly by his or her influence over other physicians.

412. Having determined that speakers were an effective way to reach prescribers, Cephalon set to work ensuring that its speakers would disseminate its misleading messages. Cephalon did not

[135] http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems (accessed May 30, 2017)
[136] *Id.*
[137] Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 347 New Eng. J. Med. 1501-04 (2016).

disclose to speakers that, even when these tools are applied, they are unable to control for the risk of addiction.

413. As with the other Defendants, Cephalon deployed the made-up concept of "pseudoaddiction" to encourage prescribers to address addictive behavior in the worst way possible—with more opioids.

414. Working with FSMB, Cephalon also trained its speakers to turn doctors' fear of discipline on its head—doctors, who believed that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with pain. Through this messaging, Cephalon aimed to normalize the prescribing of opioids for chronic pain and failed to acknowledge the serious risks of long-term opioid use and its inappropriateness as a front-line treatment for pain.

415. Finally, Cephalon also developed a guidebook called *Opioid Medications and REMS: A Patient's Guide*, which deceptively minimized the risks of addiction from the long- term use of opioids. Specifically, the guidebook claimed that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids," which is dangerously false. Cephalon distributed the guidebook broadly, and it was available to, and intended to reach, prescribers in Nassau County.

416. The misleading messages and materials Cephalon provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, without complete and accurate information about the risks, benefits, and alternatives. This deception was national in scope and included Nassau County. Cephalon's nationwide messages have reached Nassau County prescribers in a number of ways. For example, they were delivered by Cephalon's sales representatives in detailing visits and made available to County patients and prescribers through websites and ads, including ads in prominent medical journals. They have also

been delivered to County prescribers by Cephalon's paid speakers, who were required by Cephalon policy to stay true to the company's nationwide messaging.

b. Cephalon's Deceptive Third-Party Statements

417. Like the other Defendants, Cephalon also relied on third parties to disseminate its messages through deceptive publications and presentations. By funding, developing and reviewing the content, and distributing and facilitating the distribution of these messages, Cephalon exercised editorial control over them. Cephalon, in some instances, used its sales force to directly distribute certain publications by these Front Groups and KOLs, rendering those publications "labeling" within the meaning of § 21 C.F.R. § 1.3(a) and making Cephalon responsible for their contents. Cephalon also deployed its KOLs as speakers for talks and CMEs to selected groups of prescribers.

418. Cephalon's relationships with several such Front Groups and KOLs—and the misleading and deceptive publications and presentations those relationships generated—are described below.

i. *FSMB – Responsible Opioid Prescribing*

419. In 2007, for example, Cephalon sponsored and distributed through its sales representatives FSMB's *Responsible Opioid Prescribing*, which was drafted by Dr. Fishman. Dr. Fishman was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Dr. Fishman's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

420. *Responsible Opioid Prescribing* was a signature piece of Dr. Fishman's work and contained a number of deceptive statements. This publication claimed that, because pain had a negative impact on a patient's ability to function, relieving pain—alone—would "reverse that effect and improve

function." However, the truth is far more complicated; functional improvements made from increased pain relief can be offset by a number of problems, including addiction.

421. *Responsible Opioid Prescribing* also misrepresented the likelihood of addiction by mischaracterizing drug-seeking behavior as "pseudoaddiction." It explained that "requesting drugs by name," engaging in "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding were all signs of "pseudoaddiction" and are likely the effects of undertreated pain, rather than true addiction. There is no scientific evidence to support the concept of "pseudoaddiction," and any suggestion that addictive behavior masquerades as "pseudoaddiction" is false.

422. Cephalon spent $150,000 to purchase copies of *Responsible Opioid Prescribing* in bulk. It then used its sales force to distribute these copies to 10,000 prescribers and 5,000 pharmacists nationwide. These were available to, and intended to, reach prescribers and pharmacists in Nassau County.

ii. *APF – Treatment Options: A Guide for People Living with Pain*

423. Cephalon also exercised considerable control over the Front Group APF, which published and disseminated many of the most egregious falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, are described in detail below.

424. Documents indicate that Cephalon provided APF with substantial assistance in publishing deceptive information regarding the risks associated with the use of opioids for chronic pain. An April 3, 2008 Fentora Assessment Strategy Tactics Team Meeting presentation outlines Cephalon's strategy to prepare for a meeting at which the FDA Advisory Committee would consider expanding the indication of Fentora to include chronic, non-cancer pain. Cephalon prepared by "reaching out to third-party organizations, KOLs, and patients to provide context and, where appropriate, encourage related activity." First among the Front Groups listed was APF.

425. Cephalon was among the drug companies that worked with APF to "educate" the Institute of Medicine of the National Academies (IOM) on issues related to chronic opioid therapy. APF President Will Rowe circulated a document to Cephalon and other drug company personnel that contained key message points and suggested that they "[c]onsider using this document in your communications with the members of the IOM Committee." According to Rowe, recipients should "consider this a working document which you can add to or subtract from." Rowe also advised that, if recipients "have an ally on that Committee," they should "consider sharing this document with that person."

426. Cephalon personnel responded enthusiastically, with Cephalon's Associate Director for Alliance Development stating her belief that "the document does a good job of bringing together many important ideas." Cephalon reviewed and directed changes to this document, with the Cephalon Associate Director thanking Rowe "for incorporating the points we had raised." The close collaboration between Cephalon and APF on this project demonstrates their agreement to work collaboratively to promote the use of opioids as an appropriate treatment for chronic pain.

427. Cephalon's influence over APF's activities was so pervasive that APF's President, Will Rowe, even reached out to Defendants—including Cephalon—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine.

428. Starting in 2007, Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain*.[138] It is rife with misrepresentations regarding the risks, benefits, and superiority of opioids.

429. For example, *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly,

[138] https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (accessed May 30, 2017)

opioids "give [pain patients] a quality of life [they] deserve." There is no scientific evidence corroborating that statement, and such statements are, in fact, false. Available data demonstrate that patients on chronic opioid therapy are actually *less likely* to participate in life activities like work.

430. *Treatment Options* also claims that addiction is rare and is evident from patients' conduct in self-escalating their doses, seeking opioids from multiple doctors, or stealing the drugs. *Treatment Options* further minimizes the risk of addiction by claiming that it can be avoided through the use of screening tools, like "opioid agreements," which can "ensure [that patients] take the opioid as prescribed." Nowhere does *Treatment Options* explain to patients and prescribers that neither "opioid agreements" nor any other screening tools have been scientifically validated to decrease the risks of addiction, and the publication's assurances to the contrary are false and deceptive.

431. *Treatment Options* also promotes the use of opioids to treat chronic pain by painting a misleading picture of the risks of alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses, and attributes 10,000 to 20,000 deaths a year annually to NSAID overdose. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose," which is beneficial since some patients "need" larger doses of painkillers than they are currently prescribed. These claims misleadingly suggest that opioids are safe even at high doses and omit important information regarding the risks of high-dose opioids.

432. Additionally, *Treatment Options* warns that the risks associated with NSAID use increase if NSAIDs are "taken for more than a period of months," but deceptively omits any similar warning about the risks associated with the long-term use of opioids. This presentation paints a misleading picture of the risks and benefits of opioid compared with alternate treatments.

433. APF distributed 17,200 copies of *Treatment Options* in 2007 alone. It is currently available online and was intended to reach Nassau County prescribers and pharmacists.

iii. *Key Opinion Leaders and Misleading Science*

434. Cephalon also knew that its misleading messages would be more likely to be believed by prescribers if they were corroborated by seemingly neutral scientific support.

435. Employing these tactics, Cephalon caused the term "breakthrough pain"—a term it seeded in the medical literature—to be used in articles published by practitioners and clinicians it supported. With funding from Cephalon, for example, Dr. Portenoy wrote an article that purported to expand the definition of breakthrough cancer pain to non-cancer indications, vastly expanding the marketing potential of Cephalon's Fentora. The article was published in the nationally circulated *Journal of Pain* in 2006 and helped drive a surge in Fentora prescriptions.

436. The concept of "breakthrough pain" ultimately formed the sole basis for the central theme of promotional messages Cephalon cited to support the approval and marketing of Actiq and Fentora, rapid-acting opioids which begin to work very quickly but last only briefly. Neither of these drugs had a natural place in the treatment of chronic pain before Cephalon's marketing campaign changed medical practice. A recent literature survey of articles describing non-cancer breakthrough pain calls into question the validity of the concept, suggesting it is not a distinct pain condition but a hypothesis to justify greater dosing of opioids. In other words, Cephalon conjured the science of breakthrough pain in order to sell its drugs.

437. As one scholar has pointed out, references to breakthrough pain in articles published on the MEDLINE bibliographic database spiked in 1998 and again in 2006.[139] These spikes coincide with FDA's approval of Actiq and Fentora.

[139] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PharmedOut , Georgetown U. Med. Ctr. (June 25, 2010), *available at* pharmedout.galacticrealms.com/Fugh BermanPrescriptionforConflict6-25-10.pdf (accessed May 30, 2017).

iv. *Misleading Continuing Medical Education*

438. Cephalon developed sophisticated plans for the deployment of its KOLs, broken down by sub-type and specialty, to reach targeted groups of prescribers through CMEs. Cephalon used the CME programs it sponsored to deceptively portray the risks related to the use of opioids to treat chronic non-cancer pain and promote the off-label use of Actiq and Fentora.

439. In 2007 and 2008, Cephalon sponsored three CMEs that each positioned Actiq and Fentora as the only "rapid onset opioids" that would provide effective analgesia within the time period during which "breakthrough pain" was at its peak intensity. Although the CMEs used only the generic names of the drugs, the description of the active ingredient and means of administration means that a physician attending the CME knew it referred only to Actiq or Fentora.

440. The CMEs each taught attendees that there was no sound basis for the distinction between cancer and non-cancer "breakthrough pain," and one instructed patients that Actiq and Fentora were commonly used in non-cancer patients, thus effectively endorsing this use. Optimizing Opioid Treatment for Breakthrough Pain, offered online by Medscape, LLC from September 28, 2007, through December 15, 2008, was prepared by KOL Dr. Webster and M. Beth Dove. It recommends prescribing a "short-acting opioid" (e.g., morphine, hydromorphone, oxycodone) "when pain can be anticipated," or a rapid-onset opioid when it cannot. The only examples of rapid-onset opioids then on the market were oral transmucosal fentanyl citrate (i.e., Actiq) or fentanyl effervescent buccal tablet (i.e., Fentora): "Both are indicated for treatment of [breakthrough pain] in opioid-tolerant cancer patients and are frequently prescribed to treat [breakthrough pain] in noncancer patients as well."

441. Optimizing Opioid Treatment for Breakthrough Pain not only deceptively promoted Cephalon's drugs for off-label use, but also misleadingly portrayed the risks, benefits, and superiority of opioids for the treatment of chronic pain. For example, the CME misrepresented that Actiq and

Fentora would help patients regain functionality by advising that they improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. The CME also minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids.

442. Around the same time, Dr. Webster was receiving nearly $2 million in funding from Cephalon.

443. Optimizing Opioid Treatment for Breakthrough Pain was available online and was intended to reach County prescribers.

444. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online between March 31, 2008, and March 31, 2009, by Medscape, LLC. The direct result of Cephalon's funding was a purportedly educational document that echoed Cephalon's marketing messages. The CME deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid Treatment* CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach County prescribers.

445. Lastly, KOL Dr. Fine authored a CME, sponsored by Cephalon, titled *Opioid-Based Management of Persistent and Breakthrough Pain*, with KOLs Dr. Christine A. Miaskowski and Michael J. Brennan, M.D. Cephalon paid to have this CME published in a supplement of Pain Medicine News in 2009.[140] It instructed prescribers that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility," and recommended dispensing "rapid onset opioids"

[140] https://www.yumpu.com/en/document/view/11409251/opioid-based-management-of-persistent-and-breakthrough-pain (accessed May 30, 2017).

for "episodes that occur spontaneously" or unpredictably, including "oral transmucosal fentanyl," *i.e.*, Actiq, and "fentanyl buccal tablet," *i.e.*, Fentora, including in patients with chronic non-cancer pain. Dr. Miaskowski disclosed in 2009, in connection with the APS/AAPM Opioid Treatment Guidelines, that she served on Cephalon's speakers bureau.[141] Dr. Fine also received funding from Cephalon for consulting services.

446. *Opioid-Based Management of Persistent and Breakthrough Pain* was available to and was intended to reach County prescribers.

447. Cephalon's control over the content of these CMEs is apparent based on its advance knowledge of their content. A December 2005 Cephalon launch plan set forth key "supporting messages" to position Fentora for its product launch. Among them was the proposition that "15-minute onset of action addresses the unpredictable urgency of [breakthrough pain]." Years later, the same marketing messages reappeared in the Cephalon-sponsored CMEs described above. Echoing the Cephalon launch plan, Optimizing Opioid Treatment for Breakthrough Pain stated that "[t]he unpredictability of [breakthrough pain] will strongly influence the choice of treatment" and that Fentora "delivers an onset of analgesia that is similar to [Actiq] at ≤ 15 minutes." Similarly, Opioid-Based Management of Persistent and Breakthrough Pain defined "breakthrough pain" as "unpredictable," over a table describing both cancer and non-cancer "breakthrough pain."

448. Cephalon tracked the effectiveness of its deceptive marketing through third parties, demonstrating that Cephalon not only planned for, but depended upon, their activities as a key element of its marketing strategy. These programs were available to prescribers in Nassau County and, based on the uniform and nationwide character of Cephalon's marketing, featured the same deceptive messages described above.

[141] 14 of 21 panel members who drafted the AAPM/APS Guidelines received support from Janssen, Cephalon, Endo, and Purdue.

c. Cephalon's Deceptive Third-Party Statements to County Prescribers and Patients

449. Cephalon used various measures to disseminate its deceptive statements regarding the risks of off-label use of Actiq and Fentora and the risks, benefits, and superiority of opioids to County patients and prescribers.

450. Cephalon's speakers regularly held talks for County prescribers. These talks followed the same deceptive talking points covered in Cephalon's speakers' training.

451. Cephalon also targeted County prescribers through the use of its sales force.

452. Given that Cephalon's own studies demonstrated that the overwhelming majority of oncologists diagnose and treat breakthrough cancer pain themselves, Cephalon knew the only purpose of representatives meeting with these prescribers was to promote off-label use. Based on the uniform and nationwide character of Cephalon's marketing, Cephalon's deceptive messages would have been disseminated to County prescribers by Cephalon's sales representatives during these events.

453. Sales representatives, and the misrepresentations on which they were trained, drove significant Fentora sales.

3. Endo

454. Endo promoted its opioids through the full array of marketing channels. The company deployed its sales representatives, paid physician speakers, journal supplements, and advertising in support of its branded opioids, principally Opana and Opana ER. Misleading claims about the purportedly lower abuse potential of Opana ER featured prominently in this campaign. Endo also made many other deceptive statements and omissions. These included deceptive messages about functional improvement, addiction risk, "pseudoaddiction," addiction screening tools, and the safety of alternatives to opioids.

455. At the same time, Endo also relied on third-party partners to promote the safety, efficacy, and superiority of opioids generally, through a combination of CMEs, websites, patient education pamphlets, and other publications. These materials echoed the misrepresentations described above, and also made deceptive statements about withdrawal symptoms and the safety of opioids at higher doses.

456. Through the highly coordinated and uniform nature of Endo's marketing, Endo conveyed these deceptive messages to County prescribers. The materials that Endo generated in collaboration with third-parties also were distributed or made available in Nassau County. Endo distributed these messages, or facilitated their distribution, in Nassau County with the intent that County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Endo's Deceptive Direct Marketing

457. Like the other Defendants, Endo used deceptive direct marketing to increase the sales of its dangerous opioids. As set forth below, Endo conveyed these deceptive messages in training of its sales force and recruited speakers, who in turn conveyed them to physicians; in a misleading journal supplement; and in unbranded advertising.

i. *Endo's Sales Force and Deceptive Sales Training*

458. Endo's promotion of Opana ER relied heavily on in-person marketing, including to County prescribers. Endo had an aggressive detailing program. In the first quarter of 2010 alone, sales representatives made nearly 72,000 visits to prescribers nationwide to detail Opana ER. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to promote opioids through its sales force.

459. Endo's sales representatives, like those of the other Defendants, targeted physicians to deliver sales messages that were developed centrally and deployed uniformly across the country. These sales representatives were critical in transmitting Endo's marketing strategies and talking points to individual prescribers.

460. Endo specifically directed its sales force to target physicians who would prescribe its drugs to treat chronic pain. For example, an Opana Brand Tactical Plan dated August, 2007 aimed to increase "Opana ER business from [the Primary Care Physician] community" more than 45% by the end of that year. Indeed, Endo sought to develop strategies that would be most persuasive to primary care doctors—strategies that sought to influence the prescribing behavior of primary care physicians through the use of subject matter experts. A February 2011 Final Report on Opana ER Growth Trends, for example, predicted that Endo's planned "[u]se of Pain Specialists as local thought leaders should affect increased primary care adoption."

461. Endo trained its sales force to make a number of misrepresentations to physicians nationwide, including to physicians in Nassau County. Endo's sales representatives were trained to represent to these prescribers that Opana ER would help patients regain function they had lost to chronic pain; that Endo opioids had a lower potential for abuse because they were "designed to be crush resistant," despite the fact that "clinical significance of INTAC Technology or its impact on abuse/misuse ha[d] not been established for Opana ER;" and that drug seeking behavior was a sign of undertreated pain rather than addiction.

462. Endo knew that its marketing reached physicians repeatedly because it tracked their exposure. Internal Endo documents dated August 23, 2006 demonstrate that the following percentages of physicians would view an Endo journal insert (or paid supplement) at least 3 times in an 8 month period: 86% of neurologists; 86% of rheumatologists; 85% of oncologists; 85% of anesthesiologists; 70% of targeted primary care physicians; and 76% of OB/GYNs.

463. Endo was not only able to reach physicians through its marketing, but also successfully impart its marketing messages. The company found that its promotional materials tripled prescribers' ability to recall the sales message and doubled their willingness to prescribe Opana ER in the future. This was true of marketing that contained deceptions.

464. For example, according to internal Endo documents, up to 10% of physicians it detailed were able to recall, without assistance, the message that Opana ER had "Minimal/less abuse/misuse" potential than other drugs. The Endo message that prescribers retained was a plain misrepresentation: that use of Opana ER was unlikely to lead to abuse and addiction. Although Opana ER always has been classified under Schedule II as a drug with a "high potential for abuse", the largest single perceived advantage of Opana ER, according to a survey of 187 physicians who reported familiarity with the drug, was "perceived low abuse potential," cited by 15% of doctors as an advantage. Low abuse potential was among the deceptive messages that County prescribers received, and retained, from Endo sales representatives.

465. Endo's own internal documents acknowledged the misleading nature of these statements, conceding that "Opana ER has an abuse liability similar to other opioid analgesics as stated in the [FDA-mandated] box warning." A September 2012 Opana ER Business Plan similarly stated that Endo needed a significant investment in clinical data to support comparative effectiveness, scientific exchange, benefits and unmet need, while citing lack of "head-to-head data" as a barrier to greater share acquisition.

466. Nevertheless, Endo knew that its marketing was extremely effective in turning physicians into prescribers. Nationally, the physicians Endo targeted for in-person marketing represented approximately 84% of all prescribers of Opana ER in the first quarter of 2010. Endo also observed that the prescribers its sales representatives visited wrote nearly three times as many prescriptions per month for Opana ER as those physicians who were not targeted for

Endo's marketing—7.4 prescriptions per month versus 2.5. The most heavily targeted prescribers wrote nearly 30 prescriptions per month. Internal Endo documents from May 2008 indicate that Endo expected that each of its sales representatives would generate 19.6 prescriptions per week by the end of 2008. As summarized by a February 2011 report on Opana ER growth trends, Endo's "[a]ggressive detailing [is] having an impact."

467. More broadly, Endo's sales trainings and marketing plans demonstrate that its sales force was trained to provide prescribers with misleading information regarding the risks of opioids when used to treat chronic pain. Foremost among these messages were misleading claims that the risks of addiction, diversion, and abuse associated with opioids—and Endo's products in particular—were low, and lower than other opioids.

a) Endo's Sales Force Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy.

468. By way of illustration, Endo's Opana ER INTAC Technology Extended-Release Sell Sheet Implementation Guide, which instructs Endo sales personnel how to effectively "support key messages" related to the marketing of Opana ER, states that it is an "approved message" for sales representatives to stress that Opana ER was "designed to be crush resistant," even though this internal document conceded that "the clinical significance of INTAC Technology or its impact on abuse/misuse has not been established for Opana ER."

469. Other Endo documents acknowledged the limitations on Opana ER's INTAC technology, conceding that while Opana ER may be resistant to pulverization, it can still be "ground" and "cut into small pieces" by those looking to abuse the drug.

470. Endo's claims about the crush-resistant design of Opana ER also made their way to the company's press releases. A January 2013 article in *Pain Medicine News*, based in part on an Endo

press release, described Opana ER as "crush-resistant." This article was posted on the *Pain Medicine News* website, which was accessible to County patients and prescribers.

471. The only reason to promote the crush resistance of Opana ER was to persuade doctors that there was less risk of abuse, misuse, and diversion of the drug. The idea that Opana ER was less addictive than other drugs was the precise message that County prescribers took from Endo's marketing.

472. On May 10, 2013, the FDA warned Endo that there was no evidence that Opana ER's design "would provide a reduction in oral, intranasal, or intravenous abuse" and that the post-marketing data Endo had submitted to the FDA "are insufficient to support any conclusion about the overall or route-specific rates of abuse." Even though it was rebuked by the FDA, Endo continued to market Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused.

473. Endo's sales training and the promotional materials distributed by its sales representatives also minimized the risk of addiction. Endo also circulated education materials that minimized the risk of addiction. For example, Endo circulated an education pamphlet with the Endo logo titled "Living with Someone with Chronic Pain," which implied, to persons providing care to chronic pain patients, that addiction was not a substantial concern by stating that "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." This pamphlet was downloadable from Endo's website and accessible to County prescribers.

474. Endo's sales training also misrepresented the risks of addiction associated with Endo's products by implying that Opana's prolonged absorption would make it less likely to lead to abuse. For example, a presentation titled "Deliver the Difference for the Opana Brand in POA II" sets out that one of the "[k]ey [m]essages" for the Endo sales force was that Opana ER provides "[s]table,

steady-state plasma levels for true 12-hour dosing that lasts." Endo's sales representatives used this messaging to imply to County prescribers that Opana ER provided "steady state" pain relief, making Opana less likely to incite euphoria in patients and less likely to lead to addiction.

475. Endo further instructed its sales force to promote the misleading concept of "pseudoaddiction,"—i.e., that drug-seeking behavior was not cause for alarm, but merely a manifestation of undertreated pain. In a sales training document titled "Understanding the Primary Care MD and their use of Opioids," Endo noted that the "biggest concerns" among primary care physicians were "prescription drug abuse (84.2%), addiction (74.9%), adverse effects (68%), tolerance (60.7%), and medication interaction (32%)." In response to these concerns, Endo instructed its sales representatives to ask whether their customers were "confus[ing] 'pseudo-addiction' with 'drug-seekers'" and how confident they were that their health care providers "know these differences (Tolerance, Dependence, Addiction, Pseudo- Addiction . . .)."

b) Endo's Sales Force Deceptively Implied that Chronic Opioid Therapy Would Improve Patients' Ability to Function.

476. In addition to their deceptive messages regarding addiction, Endo's promotional materials and sales trainings also misleadingly claimed that patients using opioids for the long- term treatment of chronic pain would experience improvements in their daily function. In reality, long-term opioid use has not been shown to, and does not, improve patients' function, and, in fact, is often accompanied by serious side effects that degrade function. Endo's own internal documents acknowledged that claims about improved quality of life were unsubstantiated "off label claims."

477. Nevertheless, Endo distributed product advertisements that suggested that using Opana ER to treat chronic pain would allow patients to perform demanding tasks like work as a chef. One such advertisement states prominently on the front: "Janice is a 46-year-old chef with chronic low back pain. She needs a treatment option with true 12-hour dosing." The advertisement

does not mention the "moderate to severe pain" qualification in Opana ER's indication, except in the fine print. These advertisements were mailed to prescribers and distributed by Endo's sales force in detailing visits, which would have included Endo representatives' visits to prescribers.

478. In a 2007 sales tool that was intended to be shown by Endo sales personnel to physicians during their detailing visits, Endo highlighted a hypothetical patient named "Bill," a 40-year-old construction worker who was reported to suffer from chronic low back pain. According to the sales tool, Opana ER will make it more likely that Bill can return to work and support his family.

479. Similarly, training materials for sales representatives from March 2009 ask whether it is true or false that "[t]he side effects of opioids prevent a person from functioning and can cause more suffering than the pain itself." The materials indicate that this is "[f]alse" because "[t]he overall effect of treatment with opioids is very favorable in most cases."

480. A sales training video dated March 8, 2012 that Endo produced and used to train its sales force makes the same types of claims. A patient named Jeffery explains in the video that he suffers from chronic pain and that "chronic pain [. . .] reduces your functional level." Jeffery claims that after taking Opana ER, he "can go out and do things" like attend his son's basketball game and "[t]here's no substitute for that." This video was shown to Endo's sales force, which adopted its misleading messaging in its nationwide sales approach, including the approach it used in Nassau County.

481. Claims of improved functionality were central to Endo's marketing efforts for years. A 2012 Endo Business Plan lists ways to position Opana ER, and among them is the claim that Opana ER will help patients "[m]aintain[] normal functionality, sleep, [and] work/life/performance productivity" and have a positive "[e]ffect on social relationships." Indeed, that business plan describes the "Opana ER Vision" as "[t]o make the Opana franchise (Opana ER, Opana, Opana Injection) the

choice that maximizes improvement in functionality and freedom from the burden of moderate-to-severe pain."

c) Endo's Sales Force Deceptively presented the Risks and Benefits of Opioids to Make Them Appear Safer Than Other Analgesics

482. Endo further misled patients and prescribers by downplaying the risks of opioids in comparison to other pain relievers. For example, in Nassau County and elsewhere, Endo distributed a presentation titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. This study held out as a representative example one patient who had taken NSAIDs for more than eight years and, as a result, developed "a massive upper gastrointestinal bleed." The presentation recommended treating this patient with opioids instead. By focusing on the adverse side effects of NSAIDs, while omitting discussion of serious side effects associated with opioids, this presentation misleadingly portrayed the comparative risks and benefits of these drugs.

483. Endo distributed *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to 116,000 prescribers in 2007, including primary care physicians.

ii. *Endo's Speakers Bureau Programs Deceptively Minimized the Risks of Addiction Associated with Chronic Opioid Therapy*

484. In addition to its sales representatives' visits to doctors, Endo also used deceptive science and speaker programs to spread its deceptive messages.

485. Endo leaned heavily on its speakers' bureau programs. In 2008 alone, Endo spent nearly $4 million to promote up to 1,000 speakers programs around the country. Endo contracted with a medical communications firm to operate its speakers bureau program, planning to hold a total of 500 "fee-for-service . . . peer-to-peer promotional programs" for Opana ER in just the second half of 2011, including dinners, lunches and breakfasts. These programs were attended by sales representatives, revealing their true purpose as marketing, rather than educational, events.

486. Endo's internal reporting stated that the "return on investment" turned positive 8-12 weeks after such programs. Endo measured that return on investment in numbers of prescriptions written by physicians who attended the events. One internal Endo document concluded: "[w]e looked at the data for [the] 2011 program and the results were absolutely clear: physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than they had before they participated. You can't argue with results like that."

487. These speakers bureau presentations included the very same misrepresentations Endo disseminated through its sales representatives. A 2012 speaker slide deck for Opana ER— on which Endo's recruited speakers were trained and to which they were required to adhere to in their presentations—misrepresented that the drug had low abuse potential, in addition to suggesting that as many as one-quarter of the adult population could be candidates for opioid therapy.

488. In addition, a 2013 training module directed speakers to instruct prescribers that "OPANA ER with INTAC is the only oxymorphone designed to be crush resistant" and advised that "[t]he only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe OPANA ER with INTAC." This was a key point in distinguishing Opana ER from competitor drugs. Although Endo mentioned that generic versions of oxymorphone were available, it instructed speakers to stress that "[t]he generics are not designed to be crush resistant." This was particularly deceptive given that Opana ER was not actually crush-resistant.

489. In 2009, Endo wrote a talk titled *The Role of Opana ER in the Management of Chronic Pain*. The talk included a slide titled "Use of Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain," which cited the AAPM/APS Guidelines—and their accompanying misstatements regarding the likelihood of addiction (by claiming that addiction risks were manageable regardless of patients' past abuse histories) while omitting their disclaimer regarding the lack of supporting

evidence in favor of that position. This dangerously misrepresented to doctors the force and utility of the 2009 Guidelines.

490. The misleading messages and materials Endo provided to its sales force and its speakers were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Nassau County. Endo's nationwide messages would have reached County prescribers in a number of ways. For example, they were carried into Nassau County by Endo's sales representatives during detailing visits as well as made available to County patients and prescribers through websites and ads. They also have been delivered to County prescribers by Endo's paid speakers, who were required by Endo policy and by FDA regulations to stay true to Endo's nationwide messaging.

iii. *Endo's Misleading Journal Supplement*

491. In 2007, Endo commissioned the writing, and paid for the publishing of a supplement available for CME credit in the Journal of Family Practice called Pain Management Dilemmas in Primary Care: Use of Opioids, and it deceptively minimized the risk of addiction by emphasizing the effectiveness of screening tools. Specifically, it recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain. It also falsely claimed that, through the use of tools like toxicology screens, pill counts, and a "maximally structured approach," even patients at high risk of addiction could safely receive chronic opioid therapy. Endo distributed 96,000 copies of this CME nationwide, and it was available to, and was intended to, reach County prescribers.

iv. *Endo's Deceptive Unbranded Advertising*

492. Endo also used unbranded advertisements to advance its goals. By electing to focus on unbranded marketing, Endo was able to make claims about the benefits of its opioids that the

FDA would never allow in its branded materials. The chart below compares an Endo unbranded statement with one of Endo's FDA-regulated, branded statements:

Living with Someone with Chronic Pain (2009)(Unbranded)	**Opana ER Advertisement (2011/2012/2013) (Branded)**
Patient education material created by Endo	Endo advertisement
"Most health care providers who treat people with pain agree that **most people do not develop an addiction problem**."	"[C]ontains oxymorphone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit." "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."

b. Endo's Deceptive Third-Party Statements

493. Endo's efforts were not limited to directly making misrepresentations through its marketing materials, its speakers, and its sales force. Endo believed that support for patient advocacy and professional organizations would reinforce Endo's position as "the pain management company."

494. Prior to, but in contemplation of, the 2006 launch of Opana ER, Endo developed a "Public Stakeholder Strategy." Endo identified "tier one" advocates to assist in promoting the approval and acceptance of its new extended release opioid. Endo also intended to enlist the support of organizations that would be "favorable" to schedule II opioids from a sales perspective and that engaged in, or had the potential to advocate for, public policy. Endo sought to develop its relationships with these organizations through its funding. In 2008, Endo spent $1 million per year

to attend conventions of these pro-opioid medical societies, including meetings of AAPM, APS, and the American Society of Pain Management Nursing ("ASPMN").

495. APF's ability to influence professional societies and other third parties is demonstrated by its approach to responding to a citizens' petition filed with the FDA by the Physicians for Responsible Opioid Prescribing (the "PROP Petition"). The PROP petition, filed by a group of prescribers who had become concerned with the rampant prescribing of opioids to treat chronic pain, asked the FDA to require dose and duration limitations on opioid use and to change the wording of the approved indication of various long-acting opioids to focus on the severity of the pain they are intended to treat.

496. The PROP Petition set off a flurry of activity at Endo. It was understood that Endo would respond to the petition but Endo personnel wondered "[s]hould we [. . .] consider filing a direct response to this [citizens' petition] or do you think we are better served by working through our professional society affiliations?" One Endo employee responded: "My sense is the societies are better placed to make a medical case than Endo." Endo's Director of Medical Science agreed that "a reply from an external source would be most impactful." These communications reflected Endo's absolute confidence that the professional societies would support its position.

i. *APF*

497. One of the societies with which Endo worked most closely was APF. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control ("NIPC"). Endo was one of APF's biggest financial supporters, providing more than half of the $10 million APF received from opioid manufacturers during its lifespan. Endo spent $1.1 million on the NIPC program in 2008 alone, funding earmarked in part, for the creation of CME materials that were intended to be used repeatedly.

498. Endo's influence over APF's activities was so pervasive that APF President Will Rowe reached out to Defendants—including Endo—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Personnel from Defendants Purdue, Endo, Janssen, and Cephalon worked with Rowe to formulate APF's response which was ultimately published.

499. Documents also indicate that Endo personnel were given advance notice of the materials APF planned to publish on its website and provided an opportunity to comment on the content of those materials before they were published. For example, in early July of 2009, APF's Director of Strategic Development wrote to Endo personnel to give them advance notice of content that APF planned to be "putting . . . up on the website but it's not up yet." The Endo employee assured the sender that she "w[ould] not forward it to anyone at all" and promised that she would "'double delete it' from [her] inbox." In response, APF's Director of Strategic Development replied internally with only four words: "And where's the money?"

500. At no time was Endo's relationship with APF closer than during its sponsorship of the NIPC. Before being taken over by APF, the NIPC was sponsored by Professional Postgraduate Services which the Accreditation Council for Continuing Medical Education determined to be a "commercial interest" and could no longer serve as a sponsor. In response, Endo reached out to APF. An August 2009 document titled "A Proposal for the American Pain Foundation to Assume Sponsorship of the National Initiative on Pain Control," pointed out that "[f]or the past 9 years, the NIPC has been supported by unrestricted annual grants from Endo Pharmaceuticals, Inc." According to this document, APF's sponsorship of the NIPC "[o]ffers the APF a likely opportunity to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC." Further, sponsorship of the APF would "[p]rovide[] numerous synergies to disseminate patient education materials," including "[h]andouts to attendees at all live

events to encourage physicians to drive their patients to a trusted source for pain education—the APF website."

501. A September 14, 2009 presentation to APF's board contained a materially similar discussion of NIPC sponsorship, emphasizing the financial benefit to APF from assuming the role of administering NIPC. The proposal "offer[ed] a solution to continue the development and implementation of the NIPC initiative as non-certified . . . yet independent education to physicians and healthcare professionals in the primary care setting, while providing the APF with a dependable, ongoing source of grant revenue." A number of benefits related to NIPC sponsorship were listed, but chief among them was "a likely opportunity [for APF] to generate new revenue, as Endo has earmarked substantial funding: $1.2 million in net revenue for 2010 to continue the NIPC."

502. Internal Endo scheduling documents indicate that "NIPC module curriculum development, web posting, and live regional interactive workshops" were Endo promotional tasks in 2010. Endo emails indicate that Endo personnel reviewed the content created by NIPC and provided feedback.

503. Behind the scenes, Endo exercised substantial control over NIPC's work. Endo exerted its control over NIPC by funding NIPC and APF projects; developing, specifying, and reviewing content; and taking a substantial role in the distribution of NIPC and APF materials, which in effect determined which messages were actually delivered to prescribers and consumers. As described below, Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

504. From 2007 until at least 2011, Endo also meticulously tracked the distribution of NIPC materials, demonstrating Endo's commercial interest in, and access to, NIPC's reach. Endo knew exactly how many participants viewed NIPC webinars and workshops and visited its website, Painknowledge.com. Endo not only knew how many people viewed NIPC's content, but what their

backgrounds were (e.g., primary care physicians or neurologists). Endo's access to and detailed understanding of the composition of the audience at these events demonstrates how deeply Endo was involved in NIPC's activities. Moreover, Endo tracked the activities of NIPC—ostensibly a third party—just as it tracked its own commercial activity.

505. Endo worked diligently to ensure that the NIPC materials it helped to develop would have the broadest possible distribution. Endo's 2008 to 2012 Opana Brand Tactical Plan indicates that it sought to reach 1,000 prescribers in 2008 through live NIPC events, and also to "[l]everage live programs via enduring materials and web posting." Endo also planned to disseminate NIPC's work by distributing two accredited newsletters to 60,000 doctors nationwide for continuing education credit and by sponsoring a series of 18 NIPC regional case-based interactive workshops. Endo had earmarked more than one million dollars for NIPC activities in 2008 alone.

506. In short, NIPC was a key piece of Endo's marketing strategy. Indeed, internal APF emails question whether it was worthwhile for APF to continue operating NIPC given that NIPC's work was producing far more financial benefits for Endo than for APF. Specifically, after Endo approved a $244,337.40 grant request to APF to fund a series of NIPC eNewsletters, APF personnel viewed it as "[g]reat news," but cautioned that "the more I think about this whole thing, [Endo's] making a lot of money on this with still pretty slender margins on [APF's] end." APF's commitment to NIPC's "educational" mission did not figure at all in APF's consideration of the value of its work, nor was Endo's motive or benefit in doubt.

a) Misleading Medical Education

507. NIPC distributed a series of eNewsletter CMEs focused on "key topic[s] surrounding the use of opioid therapy" sponsored by Endo. These newsletters were edited by KOL Dr. Fine and listed several industry-backed KOLs, including Dr. Webster, as individual authors. Endo estimated that roughly 60,000 prescribers viewed each one. These CMEs were available to, and would have

been accessed by, County prescribers. Before-and-after surveys, summarized in the chart below, showed that prescriber comfort with prescribing opioids ranged from 27% to 62% before exposure to the CME, and from 76% to 92% afterwards:

Topic	Comfort level *prior to reading the article*	Comfort level *after reading the article*
Patient Selection and Initiation of Opioid Therapy as a Component of Pain Treatment	47%	87%
Informed Consent and Management Plans to Optimize Opioid Therapy for Chronic Pain	48%	81%
Risk Stratification and Evaluation of High-Risk Behaviors for Chronic Opioid Therapy	28%	76%
Integration of Nonpharmacologic and Multidisciplinary Therapies Into the Opioid Treatment Plan	42%	85%
Addressing Patients' Concerns Associated With Chronic Pain Treatment and Opioid Use	62%	92%
Opioid Therapy in Patients With a History of Substance Use Disorders	35%	85%
Urine Drug Testing: An Underused Tool	54%	86%
Appropriate Documentation of Opioid Therapy: The Emergence of the 4As and Trust and Verify as the Paradigm	44%	86%
Opioid Rotation	27%	92%
Discontinuing Opioid Therapy: Developing and Implementing an "Exit Strategy"	37%	90%

508. Endo documents made it clear that the persuasive power of NIPC speakers was directly proportional to their perceived objectivity. Accordingly, Endo personnel directed that, when giving Endo-sponsored talks, NIPC faculty would not appear to be "Endo Speakers." Nevertheless, the two parties understood that Endo and NIPC shared a common "mission to educate physicians" and working "through the APF . . . [wa]s a great way to work out . . .problems that could have been there without the APF's participation and support."

509. The materials made available on and through NIPC included misrepresentations. For example, Endo worked with NIPC to sponsor a series of CMEs titled *Persistent Pain in the Older Patient* and *Persistent Pain in the Older Adult*. These CMEs misrepresented the prevalence of addiction by stating that opioids have "possibly less potential for abuse" in elderly patients than in younger patients, even

though there is no evidence to support such an assertion. Moreover, whereas withdrawal symptoms are always a factor in discontinuing long-term opioid therapy, *Persistent Pain in the Older Adult* also misleadingly indicated that such symptoms can be avoided entirely by tapering the patient's does by 10-20% per day for ten days. *Persistent Pain in the Older Patient*, for its part, made misleading claims that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." NIPC webcast these CMEs from its own website, where they were available to, and were intended to reach, County prescribers.

b) *Painknowledge.com*

510. Working with NIPC enabled Endo to make a number of misleading statements through the NIPC's website, *Painknowledge.com*. Endo tracked visitors to *PainKnowledge.com* and used *Painknowledge.com* to broadcast notifications about additional NIPC programming that Endo helped to create.

511. APF made a grant request to Endo to create an online opioid "tool-kit" for NIPC and to promote NIPC's website, *Painknowledge.com*. In so doing, APF made clear that it planned to disseminate Defendants' misleading messaging. The grant request expressly indicated APF's intent to make misleading claims about functionality, noting: "Some of these people [in chronic pain] may be potential candidates for opioid analgesics, which can improve pain, function, and quality of life." Endo provided $747,517 to fund the project.

512. True to APF's word, *Painknowledge.com* misrepresented that opioid therapy for chronic pain would lead to improvements in patients' ability to function. Specifically, in 2009 the website instructed patients and prescribers that, with opioids, a patient's "level of function should improve" and that patients "may find [they] are now able to participate in activities of daily living, such as work and hobbies, that [they] were not able to enjoy when [their] pain was worse."

513. *Painknowledge.com* also deceptively minimized the risk of addiction by claiming that "[p]eople who take opioids as prescribed usually do not become addicted." *Painknowledge.com* did not stop there. It deceptively portrayed opioids as safe at high doses and also misleadingly omitted serious risks, including the risks of addiction and death, from its description of the risks associated with the use of opioids to treat chronic pain.

514. Endo was the sole funder of Painknowledge.com, and it continued to provide that funding despite being aware of the website's misleading contents.

c) *Exit Wounds*

515. Finally, Endo also sponsored APF's publication and distribution of *Exit Wounds*, a publication aimed at veterans that also contained a number of misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by Derek Mcginnis." Derek Mcginnis was frequently hired by a consulting Firm, Conrad & Associates LLC, to write pro-opioid marketing pieces disguised as science. Derek Mcginnis's work was reviewed and approved by drug company representatives, and he felt compelled to draft pieces that he admits distorted the risks and benefits of chronic opioid therapy in order to meet the demands of his drug company sponsors.

516. *Exit Wounds* is a textbook example of Derek Mcginnis's authorship on drug companies' behalf. The book misrepresented the functional benefits of opioids by stating that opioid medications "*increase* your level of functioning" (emphasis in original).

517. *Exit Wounds* also misrepresented that the risk of addiction associated with the use of opioids to treat chronic pain was low. It claimed that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications."

518. Finally, *Exit Wounds* misrepresented the safety profile of using opioids to treat chronic pain by omitting key risks associated with their use. Specifically, it omitted warnings of the risk of interactions between opioids and benzodiazepines—a warning sufficiently important to be included on Endo's FDA-required labels. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids—a particular risk for veterans.

519. As outlined above, Endo exercised dominance over APF and the projects it undertook in an effort to promote the use of opioids to treat chronic pain. In addition, as outlined above, Derek Mcginnis's work was being reviewed and approved by drug company representatives, motivating him to draft pro-opioid propaganda masquerading as science. Combined, these factors gave Endo considerable influence over the work of Derek Mcginnis and over APF. Further, by paying to distribute *Exit Wounds*, Endo endorsed and approved its contents.

ii. *Other Front Groups: FSMB, AAPM, and AGS*

520. In addition to its involvement with APF, Endo worked closely with other third-party Front Groups and KOLs to disseminate deceptive messages regarding the risks, benefits, and superiority of opioids for the treatment of chronic pain. As with certain APF publications, Endo in some instances used its sales force to directly distribute certain publications by these Front Groups and KOLs, making those publications "labeling" within the meaning of 21 C.F.R.§ 1.3(a).

521. In 2007, Endo sponsored FSMB's *Responsible Opioid Prescribing*, which in various ways deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* was drafted by "Dr. Fishman."

522. Endo spent $246,620 to help FSMB distribute *Responsible Opioid Prescribing*. Endo approved this book for distribution by its sales force. Based on the uniform and nationwide character of Endo's marketing campaign, and the fact that Endo purchased these copies specifically

to distribute them, these copies were distributed to physicians nationwide, including physicians in Nassau County.

523. In December 2009, Endo also contracted with AGS to create a CME to promote the 2009 guidelines titled the *Pharmacological Management of Persistent Pain in Older Persons* with a $44,850 donation. These guidelines misleadingly claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse," as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)" when in reality, opioid therapy was only an appropriate treatment for a subset of those patients, as recognized by Endo's FDA-mandated labels.

524. AGS's grant request to Endo made explicit reference to the CME that Endo was funding. Endo thus knew full well what content it was paying to distribute, and was in a position to evaluate that content to ensure it was accurate, substantiated, and balanced before deciding whether or not to invest in it. After having sponsored the AGS CME, Endo's internal documents indicate that Endo's pharmaceutical sales representatives discussed the AGS guidelines with doctors during individual sales visits.

525. Endo also worked with AAPM, which it viewed internally as "Industry Friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications.

526. A talk written by Endo in 2009 and approved by Endo's Medical Affairs Review Committee,[142] titled *The Role of Opana ER in the Management of Chronic Pain,* includes a slide titled *Use of*

[142] Although they were given slightly different names by each Defendant, each Defendant employed a committee that could review and approve materials for distribution. These committees included representatives from all relevant departments within Defendants' organizations, including the legal, compliance, medical affairs, and marketing departments. The task of these review committees was to

Opioids is Recommended for Moderate to Severe Chronic Noncancer Pain. That slide cites the AAPM/APS Guidelines, which contain a number of misstatements and omits their disclaimer regarding the lack of supporting evidence. This talk dangerously misrepresented to doctors the force and utility of the 2009 Guidelines. Furthermore, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

iii. *Key Opinion Leaders and Misleading Science*

527. Endo also sought to promote opioids for the treatment of chronic pain through the use of key opinion leaders and biased, misleading science.

528. Endo's 2010 publication plan for Opana ER identified a corporate goal of making Opana ER the second-leading branded product for the treatment of moderate-to-severe chronic pain (after OxyContin). Endo sought to achieve that goal by providing "clinical evidence for the use of Opana ER in chronic low back pain and osteoarthritis," and subsequently successfully had articles on this topic published.[143]

529. In the years that followed, Endo sponsored articles authored by Endo consultants and Endo employees, which argued that the metabolic pathways utilized by Opana ER, compared with other opioids, were less likely to result in drug interactions in elderly low back and osteoarthritis pain patients. In 2010, Endo directed its publication manager to reach out to a list of consultants

---

scrutinize the marketing materials Defendants planned to distribute and to ensure that those materials were scientifically accurate and legally sound. Tellingly, these committees were called to review only materials that created a potential compliance issue for the company, an implicit recognition by defendants that they ultimately would be responsible for the content under review.

[143] These studies suffered from the limitations common to the opioid literature—and worse. None of the comparison trials lasted longer than three weeks. Endo also commissioned a six-month, open label trial during which a full quarter of the patients failed to find a stable dose, and 17% of patients discontinued, citing intolerable effects. In open label trials, subjects know which drug they are taking; such trials are not as rigorous as double-blind, controlled studies in which neither the patients nor the examiners know which drugs the patients are taking.

conducting an ongoing Endo-funded study, to assess their willingness to respond to an article[144] that Endo believed emphasized the risk of death from opioids, "without [] fair balance."[145]

530. Endo's reliance on flawed, biased research is also evident in its 2012 marketing materials and strategic plans. A 2012 Opana ER slide deck for Endo's speakers bureaus—on which these recruited physician speakers were trained and to which they were required to adhere—misrepresented that the drug had low abuse potential and suggested that as many as one-quarter of the adult population could be candidates for opioid therapy. Although the FDA requires such speaker slide decks to reflect a "fair balance" of information on benefits and risks, Endo's slides reflected one-sided and deeply biased information. The presentation's 28 literature citations were largely to "data on file" with the company, posters, and research funded by, or otherwise connected to, Endo. Endo's speakers relayed the information in these slides to audiences that were unaware of the skewed science on which the information was based.

531. A 2012 Opana ER Strategic Platform Review suffered from similar defects. Only a small number of the endnote referenced in the document, which it cited to indicate "no gap" in scientific evidence for particular claims, were to national-level journals. Many were published in lesser or dated journals, and written or directly financially supported by opioid manufacturers. Where the strategy document did cite independent, peer-reviewed research, it did so out of context. For example, it cited a 2008 review article on opioid efficacy for several claims, including that "treatment of chronic pain reduces pain and improves functionality," but it ignored the article's overall focus on the lack of consistent effectiveness of opioids in reducing pain and improving functional status.[146]

---

[144] Susan Okie, *A Flood of Opioids, a Rising Tide of Deaths*, 363 New Engl. J. Med. 1981 (2010), finding that opioid overdose deaths and opioid prescriptions both increased by roughly 10-fold from 1990 to 2007.

[145] Endo did manage to get a letter written by three of those researchers, which was not published.

[146] Andrea M. Trescot et al., Opioids in the management of non-cancer pain: an Update of American Society of the Interventional Pain Physicians, Pain Physician 2008 Opioids Special Issue, 11:S5-S62.

532. Notwithstanding Endo's reliance upon dubious or cherry-picked science, in an Opana ER brand strategy plan it internally acknowledged the continuing need for a significant investment in clinical data to support comparative effectiveness. Endo also cited a lack of "head-to-head data" as a barrier to greater share acquisition, and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation. This acknowledged lack of support did not stop Endo from directing its sales representatives to tell prescribers that its drugs were less likely to be abused or be addictive than other opioids.

533. Endo also worked with various KOLs to disseminate various misleading statements about chronic opioid therapy. For example, Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding your Pain: Taking Oral Opioid Analgesics*. This pamphlet deceptively minimized the risks of addiction by stating that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems," implying that patients who are taking opioids for pain are not at risk of addiction.

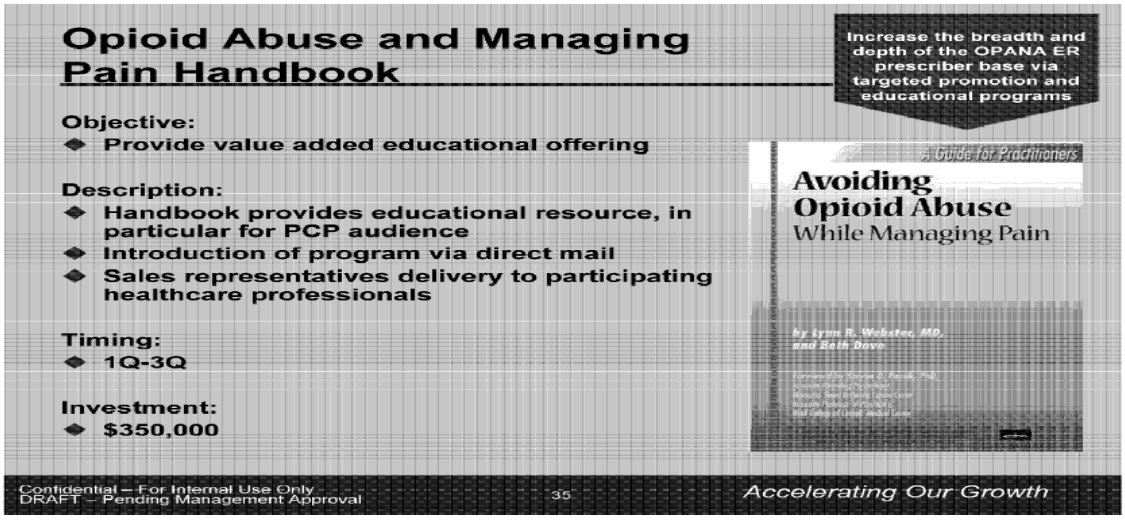
534. *Understanding your Pain: Taking Oral Opioid Analgesics* also misleadingly omitted any description of the increased risks posed by higher doses of opioid medication. Instead, in a Q&A format, the pamphlet asked "[i]f I take the opioid now, will it work later when I really need it?" and responded that "[t]he dose can be increased... [y]ou won't 'run out' of pain relief."

535. Dr. Portenoy received research support, consulting fees, and honoraria from Endo for editing *Understanding Your Pain* and other projects.

536. *Understanding Your Pain* was available on Endo's website during the time period of this Complaint and was intended to reach County prescribers.

537. Endo similarly distributed a book written by Dr. Lynn Webster titled Avoiding *Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."

538. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." The slide indicates that the book would be particularly effective "for [the] PCP audience" and instructed "[s]ales representatives [to] deliver[the book] to participating health care professionals." The slide, shown below, demonstrates Endo's express incorporation of this book by a KOL into its marketing strategy:



539. Endo Documents indicate that, around 2007, the company purchased at least 50,000 copies of the book for distribution. Internal Endo documents Demonstrate that the book had been approved for distribution by Endo's sales force, and that Endo had fewer than 8,000 copies on hand in March of 2013. Based on the nationwide and uniform character of Endo's marketing, and the book's approval for distribution, this book was available to and was intended to reach prescribers.

c. Endo's Deceptive Statements to County Prescribers and Patients

540. Endo also directed the dissemination of the misstatements described above to County patients and prescribers, including through its sales force, speakers bureaus, CMEs, and the *Painknowledge.com* website.

541. Consistent with their training, Endo's sales representatives delivered all of these deceptive messages to County prescribers.

542. Endo also directed misleading marketing to County prescribers and patients through the APF/NIPC materials it sponsored, reviewed, and approved. For example, Endo hired a New York-based KOL to deliver a CME titled *Managing Persistent Pain in the Older Patient* on April 27, 2010. As described above, this CME misrepresented the prevalence of addiction in older patients and made misleading claims that chronic opioid therapy would improve patients' ability to function. An email invitation to the event and other NIPC programs was sent to "all healthcare professionals" in APF's database.

543. The significant response to *Painknowledge.com* also indicates that those websites were viewed by County prescribers, who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids. As of September 14, 2010, *Painknowledge.com* had 10,426 registrants, 86,881 visits, 60,010 visitors, and 364,241 page views. Upon information and belief, based on the site's nationwide availability, among the site's visitors were County patients and prescribers who were exposed to the site's misleading information regarding the effect of opioids on patients' ability to function and the deceptive portrayal of the risks of opioids.

544. Endo knew that the harms from its deceptive marketing would be felt in Nassau County. It saw workers' compensation programs as a lucrative opportunity, and it promoted the use of opioids for chronic pain arising from work-related injuries, like chronic lower back pain. Endo

developed plans to "[d]rive demand for access through the employer audience by highlighting cost of disease and productivity loss in those with pain; [with a] specific focus on high-risk employers and employees." In 2007, Endo planned to reach 5,000 workers' compensation carriers to ensure that Opana ER would be covered under disability insurance plans. Endo knew or should have known that claims for its opioids would be paid for by the County's workers' compensation program.

4. Janssen

545. Janssen promoted its branded opioids, including Duragesic, Nucynta, and Nucynta ER, through its sales representatives and a particularly active speakers program. Deceptive messages regarding low addiction risk and low prevalence of withdrawal symptoms were a foundation of this marketing campaign. Janssen also conveyed other misrepresentations including that its opioids could safely be prescribed at higher doses and were safer than alternatives such as NSAIDs.

546. Janssen supplemented these efforts with its own unbranded website, as well as third-party publications and a Front Group website, to promote opioids for the treatment of chronic pain. These materials likewise made deceptive claims about addiction risk, safety at higher doses, and the safety of alternative treatments. They also claimed that opioid treatment would result in functional improvement, and further masked the risk of addiction by promoting the concept of pseudoaddiction.

547. Based on the highly coordinated and uniform nature of Janssen's marketing, Janssen conveyed these deceptive messages to County prescribers. The materials that Janssen generated in collaboration with third-parties also were distributed or made available in Nassau County. Janssen distributed these messages, or facilitated their distribution, in Nassau County with the intent that County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

a. Janssen's Deceptive Direct Marketing

548. Janssen joined the other Defendants in propagating deceptive branded marketing that falsely minimized the risks and overstated the benefits associated with the long-term use of opioids to treat chronic pain. Like the other Defendants, Janssen sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed identically across the country. These sales representatives were critical in transmitting Janssen's marketing strategies and talking points to individual prescribers. In 2011, at the peak of its effort to promote Nucynta ER, Janssen spent more than $90 million on detailing.

549. Janssen's designs to increase sales through deceptive marketing are apparent on the face of its marketing plans. For example, although Janssen knew that there was no credible scientific evidence establishing that addiction rates were low among patients who used opioids to treat chronic pain, its Nucynta Business Plans indicated that one of the "drivers" to sell more Nucynta among primary care physicians was the "[l]ow perceived addiction and/or abuse potential" associated with the drug. However, there is no evidence that Nucynta is any less addictive or prone to abuse than other opioids, or that the risk of addiction or abuse is low. Similarly, Janssen knew that there were severe symptoms associated with opioid withdrawal including, severe anxiety, nausea, vomiting, hallucinations, and delirium, but Janssen touted the ease with which patients could come off opioids.

i. *Janssen's Deceptive Sales Training*

550. Janssen's sales force was compensated based on the number of Nucynta prescriptions written in each sales representative's territory. Janssen encouraged these sales representatives to maximize sales of Nucynta and meet their sales targets by relying on the false and misleading statements described above.

551. For example, Janssen's sales force was trained to trivialize addiction risk. A June 2009 Nucynta training module warns that physicians are reluctant to prescribe controlled substances like

Nuycnta because of their fear of addicting patients, but this reluctance is unfounded because "the risks . . . are [actually] much smaller than commonly believed." Janssen also encouraged its sales force to misrepresent the prevalence of withdrawal symptoms associated with Nucynta. A Janssen sales training PowerPoint titled "Selling Nucynta ER and Nucynta" indicates that the "low incidence of opioid withdrawal symptoms" is a "core message" for its sales force. The message was touted at Janssen's Pain District Hub Meetings, in which Janssen periodically gathered its sales force personnel to discuss sales strategy.

552. This "core message" of a lack of withdrawal symptoms runs throughout Janssen's sales training materials. For example, Janssen's "Licensed to Sell" Facilitator's Guide instructs those conducting Janssen sales trainings to evaluate trainees, in part, on whether they remembered that "[w]ithdrawal symptoms after abrupt cessation of treatment with NUCYNTA ER were mild or moderate in nature, occurring in 11.8% and 2% of patients, respectively" and whether they were able to "accurately convey" this "core message." Janssen further claimed in 2008 that "low incidence of opioid withdrawal symptoms" was an advantage of the tapentadol molecule.

553. Similarly, a Nucynta Clinical Studies Facilitator's Guide instructs individuals training Janssen's sales representatives to ask trainees to describe a "key point"—that "83% of patients reported no withdrawal symptoms after abruptly stopping treatment without initiating alternative therapy"—"as though he/she is discussing it with a physician."

554. This misrepresentation regarding withdrawal was one of the key messages Janssen imparted to employees in the "Retail ST 101 Training" delivered to Nucynta sales representatives.

555. Indeed, training modules between 2009 and 2011 instruct training attendees that "most patients [who discontinued taking Nucynta] experienced no withdrawal symptoms" and "[n]o patients experienced moderately severe or severe withdrawal symptoms."

556. During the very time Janssen was instructing its sales force to trivialize the risks of addiction and withdrawal associated with the use of Nucynta to treat chronic pain, it knew or should have known, that significant numbers of patients using opioids to treat chronic pain experienced issues with addiction. Janssen knew or should have known that its studies on withdrawal were flawed and created a misleading impression of the rate of withdrawal symptoms and, as a result, the risk of addiction.

557. The misleading messages and materials Janssen provided to its sales force were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Nassau County. Janssen's nationwide messages reached County prescribers in a number of ways, including through its sales force in detailing visits, as well as through websites and ads. They were also delivered to County prescribers by Janssen's paid speakers, who were required by Janssen policy and by FDA regulations to stay true to Janssen's nationwide messaging.

ii. *Janssen's Deceptive Speakers Bureau Programs*

558. Janssen did not stop at disseminating its misleading messages regarding chronic opioid therapy through its sales force. It also hired speakers to promote its drugs and trained them to make the very same misrepresentations made by its sales representatives.

559. Janssen's speakers worked from slide decks—which they were required to present—reflecting the deceptive information about the risks, benefits, and superiority of opioids outlined above. For example, a March 2011 speaker's presentation titled *A New Perspective For Moderate to Severe Acute Pain Relief: A Focus on the Balance of Efficacy and Tolerability* set out the following adverse events associated with use of Nucynta: nausea, vomiting, constipation, diarrhea, dizziness, headache, anxiety, restlessness, insomnia, myalgia, and bone pain. It completely omitted the risks of misuse, abuse, addiction, hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding,

confusion, and other known, serious risks associated with chronic opioid therapy. The presentation also minimized the risks of withdrawal by stating that "more than 82% of subjects treated with tapentadol IR reported no opioid withdrawal symptoms."

560. An August 2011 speaker presentation titled *New Perspectives in the Management of Moderate to Severe Chronic Pain* contained the same misleading discussion of the risks associated with chronic opioid therapy. It similarly minimized the risks of withdrawal by reporting that 86% of patients who stopped taking Nucynta ER "abruptly without initiating alternative opioid therapy" reported no withdrawal symptoms whatsoever. The same deceptive claims regarding risks of adverse events and withdrawal appeared in a July 2012 speaker's presentation titled *Powerful Pain Management: Proven Across Multiple Acute and Chronic Pain Models*.

561. These speakers presentations were part of Janssen's nationwide marketing efforts. Upon information and belief, a number of these events were available to and were intended to reach Nassau County prescribers.

iii. *Janssen's Deceptive Unbranded Advertising*

562. Janssen was aware that its branded advertisements and speakers programs would face regulatory scrutiny that would not apply to its unbranded materials, so Janssen also engaged in direct, unbranded marketing.

563. One such unbranded project was Janssen's creation and maintenance of *Prescriberesponsibly.com* (last updated July 2, 2015), a website aimed at prescribers and patients that claims that concerns about opioid addiction are "overstated." A disclaimer at the bottom of the website states that the "site is published by Janssen Pharmaceuticals, Inc., which is solely responsible for its content." This website was available to and intended to reach County prescribers and patients.

b. Janssen's Deceptive Third-Party Statements

564. Janssen's efforts were not limited to directly making misrepresentations through its sales force, speakers' bureau, and website. To avoid regulatory constraints and give its efforts an appearance of independence and objectivity, Janssen obscured its involvement in certain marketing activities by "collaborat[ing] with key patient advocacy organizations" to release misleading information about opioids.

i. *AAPM and AGS – Finding Relief: Pain Management for Older Adults*

565. Janssen worked with AAPM and AGS to create a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009). In doing so, Janssen contracted with a medical publishing firm, Conrad & Associates, LLC. The content was drafted by a writer ("Medical Writer X") hired by Conrad & Associates and funded by Janssen. These materials were reviewed, in detail, by Janssen's medical-legal review team, which conducted detailed reviews and gave him editorial feedback on his drafts, which was adopted in the published version.

566. Medical Writer X understood, without being explicitly told, that since his work was funded and reviewed by Janssen, the materials he was writing should aim to promote the sale of more drugs by overcoming the reluctance to prescribe or use opioids to treat chronic pain. He knew that the publication was undertaken in connection with the launch of a new drug and was part of its promotional effort. Medical Writer X knew of the drug company's sponsorship of the publication, and he would go to the company's website to learn about the drug being promoted. He also knew that his clients—including Janssen—would be most satisfied with his work if he emphasized that: (a) even when used long-term, opioids are safe and the risk of addiction is low; (b) opioids are effective

for chronic pain; and (c) opioids are under-prescribed because doctors are hesitant, confused, or face other barriers.[147]

567. *Finding Relief* is rife with the deceptive content. *Finding Relief* misrepresents that opioids increase function by featuring a man playing golf on the cover and listing examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The functional claims contained in *Finding Relief* are textbook examples of Defendants' use of third parties to disseminate messages the FDA would not allow them to say themselves. Compare, e.g.:

Branded Advertisement That Triggers an FDA Warning Letter (2008)[148]
Improvement in Daily Activities Includes: • Walking on a flat surface • Standing or sitting • Climbing stairs • Getting in and out of bed or bath • Ability to perform domestic duties

with:

[147] Medical Writer X now acknowledges that the lists of adverse effects from chronic opioid use in the publications he authored, which excluded respiratory depression, overdose, and death and minimized addiction, were, "ridiculous" and "prime examples" of leaving out facts that the pharmaceutical company sponsors and KOLs knew at the time were true. His writings repeatedly described the risk of addiction as low. Medical Writer X stated that he understood that the goal was to promote opioids and, as a result, discussing addiction would be "counterproductive."

[148] This advertisement drew an FDA Warning Letter dated March 24, 2008. Though the advertisement was by drug company King, it is used here to demonstrate the types of claims that the FDA regarded as unsupported.

Seemingly Independent Publication: "Finding Relief: Pain Management for Older Adults" (Final Authority, Janssen 2009):
Your recovery will be measured by how well you reach functional goals such as • Sleeping without waking from pain • Walking more, or with less pain • Climbing stairs with less pain • Returning to work • Enjoying recreational activities • Having sex • Sleeping in your own bed

568. *Finding Relief* also trivialized the risks of addiction describing as a "myth" that opioids are addictive, and asserting as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

569. *Finding Relief* further misrepresented that opioids were safe at high doses by listing dose limitations as "disadvantages" of other pain medicines and omitting any discussion of risks from increased doses of opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."

570. Finally, *Finding Relief* deceptively overstated the risks associated with alternative forms of treatment. It juxtaposed the advantages and disadvantages of NSAIDs on one page, with the "myths/facts" of opioids on the facing page. The disadvantages of NSAIDs are described as involving "stomach upset or bleeding," "kidney or liver damage if taken at high doses or for a long time," "adverse reactions in people with asthma," and "increase[d] . . .risk of heart attack and stroke." Conversely, the only adverse effects of opioids listed by *Finding Relief* are "upset stomach or

sleepiness," which the brochure claims will go away, and constipation. The guide never mentions addiction, overdose, abuse, or other serious side effects of opioids.

571. Janssen was not merely a passive sponsor of *Finding Relief*. Instead, Janssen exercised control over its content and provided substantial assistance to AGS and AAPM to distribute it. A "Copy Review Approval Form" dated October 22, 2008 indicates that key personnel from Janssen's Advertising & Promotion, Legal, Health Care Compliance, Medical Affairs, Medical Communications, and Regulatory Departments reviewed and approved *Finding Relief*. All six Janssen personnel approving the publication checked the box on the approval form indicating that *Finding Relief* was "Approved With Changes." After the publication was modified at the behest of Janssen personnel, Janssen paid to have its sales force distribute 50,000 copies of *Finding Relief* throughout the nation. Thus, *Finding Relief* is considered labeling for Janssen's opioids within the meaning of 21 C.F.R. § 1.3(a).

572. AAPM purchased and distributed copies of *Finding Relief* to all of its members, including those who reside in Nassau County.

573. *Finding Relief's* author, Medical Writer X, later said it was clear, from his position at the intersection of science and marketing, that the money paid by drug companies to the KOLs and professional and patient organizations with which he worked, distorted the information provided to doctors and patients regarding opioids. The money behind these and many other "educational" efforts also, he believes, led to a widespread lack of skepticism on the part of leading physicians about the hazards of opioids. It also led these physicians to accept, without adequate scrutiny, published studies that, while being cited to support the safety of opioids, were, in fact, of such poor methodological quality that they would not normally be accepted as adequate scientific evidence.

ii. *AGS – Misleading Medical Education*

574. Janssen also worked with AGS on another project—AGS's CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" although the study supporting this assertion did not analyze addiction rates by age. They also stated falsely, that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)." Based on Janssen's control over AGS's *Finding Relief*, Janssen also would have exercised control over this project as well.

iii. *APF*

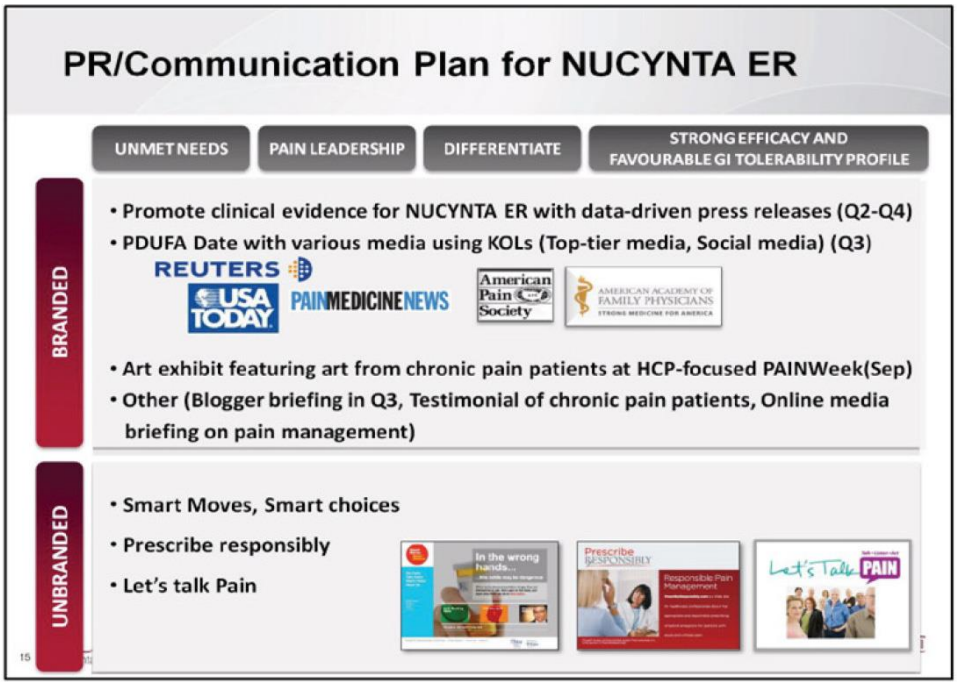
575. Janssen also worked with APF to carry out its deceptive marketing campaign. Documents obtained from one of Janssen's public relations firms, Ketchum, indicate that Janssen and the firm enlisted APF as part of an effort to "draft media materials and execute [a] launch plan" for Janssen's drugs at an upcoming meeting of the AAPM. Janssen also drew on APF publications to corroborate claims in its own marketing materials and its sales training. Janssen personnel participated in a March 2011 call with APF's "Corporate Roundtable," in which they worked with APF and drug company personnel to develop strategies to promote chronic opioid therapy. APF personnel spoke with Janssen employees who "shar[ed] expertise from within their company for [a] public awareness campaign."

576. Their joint work on the "Corporate Roundtable" demonstrates the close collaboration between Janssen and APF in promoting opioids for the treatment of chronic pain. APF President Will Rowe also reached out to Defendants—including Janssen— rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine. Additional examples of APF's collaboration with Janssen are laid out below:

a) Let's Talk Pain

577. Most prominent among these efforts was the *Let's Talk Pain* website. Janssen sponsored *Let's Talk Pain* in 2009, acting in conjunction with APF, American Academy of Pain Management, and American Society of Pain Management Nursing. Janssen financed and orchestrated the participation of these groups in the website.

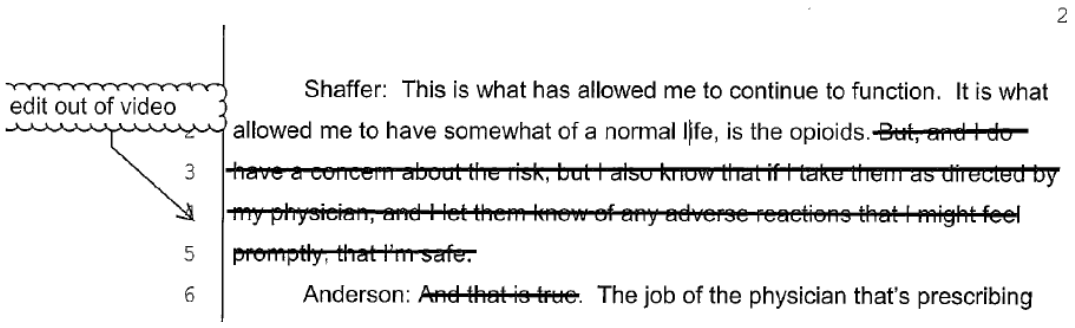
578. Janssen exercised substantial control over the content of the *Let's Talk Pain* website. Janssen's internal communications always referred to *Let's Talk Pain* as promoting tapentadol, the molecule it sold as Nucynta and Nucynta ER. Janssen regarded *Let's Talk Pain* and another website—*Prescriberesponsibly.com*— as integral parts of Nucynta's launch:



579. Janssen documents also reveal that Janssen personnel viewed APF and AAPM as "coalition members" in the fight to increase market share.

580. To this end, Janssen and APF entered into a partnership to "keep pain and the importance of responsible pain management top of mind" among prescribers and patients. They

agreed to work to reach "target audiences" that included patients, pain management physicians, primary care physicians, and KOLs. One of the roles Janssen assumed in the process was to "[r]eview, provide counsel on, and approve materials." Janssen did in fact review and approve material for the *Let's Talk Pain* website, as evidenced by the following edits by a Janssen executive to the transcript of a video that was to appear on the site:



581. The final version of the video on *Let's Talk Pain* omitted the stricken language above.

582. This review and approval authority extended to the *Let's Talk Pain* website. Emails between Janssen personnel and a consultant indicate that, even though the *Let's Talk Pain* website was hosted by APF, Janssen had approval rights over its content. Moreover, emails describing Janssen's review and approval rights related to *Let's Talk Pain* indicate that this right extended to "major changes and video additions."

583. As a 2009 Janssen memo conceded, "[t]he *Let's Talk Pain Coalition* is sponsored by PriCara, a Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc." and "[t]he Coalition and Pricara **maintain editorial control of all *Let's Talk Pain* materials and publications**" (emphasis added).

584. A 2011 Consulting Agreement between Janssen and one of APF's employees, relating to the dissemination of national survey data, demonstrates the near-total control Janssen was empowered to exercise over APF in connection with the *Let's Talk Pain* website, including requiring APF to circulate and post Janssen's promotional content. The agreement required APF to "participate in status calls between Janssen, APF, AAPM, ASPMN, and Ketchum as requested by

Janssen" and required APF to "respond to requests to schedule status calls **within 48 hours** of the request" (emphasis in original). APF also was required to "[r]eview and provide feedback to media materials, including a press release, pitch email, a key messages document, and social media messages, **within one week** of receipt" (emphasis in original).

585. The agreement further required APF to provide a summary of the survey results in APF's PAIN MONITOR e-newsletter, post a link to the survey results on APF's Facebook page, send out tweets related to the survey, serve as a spokesperson available for media interviews, "[s]hare information with any media contacts with whom APF has existing relationships to promote the announcement of the national survey findings," identify at least two patient spokespersons to talk about the survey data, and include the survey results in "any future APF materials, as appropriate." Tellingly, "any ideas made or conceived by [APF] in connection with or during the performance" of the Agreement "shall be the property of, and belong to, [Janssen]."

586. Janssen also exercised its control over *Let's Talk Pain*. Janssen was able to update the *Let's Talk Pain* website to describe its corporate restructuring and Janssen personnel asserted their control over "video additions" by reviewing and editing the interview touting the functional benefits of opioids. Given its editorial control over the content of *Let's Talk Pain*, Janssen was, at all times, fully aware of—and fully involved in shaping—the website's content.[149]

587. Let's Talk Pain contained a number of misrepresentations.

588. For example, *Let's Talk Pain* misrepresented that the use of opioids for the treatment of chronic pain would lead to patients regaining functionality. Let's Talk Pain featured an interview claiming that opioids were what allowed a patient to "continue to function."

[149] It bears noting that Janssen does not publicly identify its role in creating *Let's Talk Pain*'s content. Instead, *Let's Talk Pain* represents that "coalition members" develop the content that appears on the website and lists Janssen as the only sponsor of that coalition.

589. In 2009, *Let's Talk Pain* also promoted the concept of "pseudoaddiction," which it described as patient behaviors that may occur when pain is under-treated" but differs "from true addiction because such behaviors can be resolved with effective pain management" (emphasis added). *Let's Talk Pain* was available to, and was intended to, reach Nassau County patients and prescribers.

b) Exit Wounds

590. Janssen also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Exit Wounds* was drafted by "Medical Writer X." It is fully representative of his work on behalf of drug companies.

591. Janssen gave APF substantial assistance in distributing *Exit Wounds* in Nassau County and throughout the nation by providing grant money and other resources.

c. Janssen's Deceptive Statements to Nassau County Prescribers and Patients

592. Janssen also directed the misstatements described above to Nassau County patients and prescribers, including through CMEs, its sales force, and recruited physician speakers.

i. *Janssen's Deceptive Medical Education Programs in Nassau County*

593. Janssen sponsored CMEs and talks attended by County prescribers.

ii. *Janssen's Deceptive Detailing Practices in Nassau County*

594. The experiences of specific prescribers confirm both that Janssen's national marketing campaign included the misrepresentations, and that the company disseminated these same misrepresentations to Nassau County prescribers and consumers. In particular, these prescriber accounts reflect that Janssen detailers claimed that Nucynta was "not an opioid" because it worked

on an "alternate receptor";[150] claimed that Janssen's drugs would be less problematic for patients because they had anti-abuse properties and were "steady state"; claimed that patients on Janssen's drugs were less susceptible to withdrawal; omitted or minimized the risk of opioid addiction; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

5. Purdue

595. Purdue promoted its branded opioids—principally, Oxycontin, Butrans, and Hysingla—and opioids generally in a campaign that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Purdue did this through its sales force, branded advertisements, promotional materials, and speakers, as well as a host of materials produced by its third-party partners, most prominently APF. Purdue's sales representatives and advertising also misleadingly implied that OxyContin provides a full 12 hours of pain relief, and its allied Front Groups and KOLs conveyed the additional deceptive messages about opioids' safety at higher doses, the safety of alternative therapies, and the effectiveness of addiction screening tools.

596. Based on the highly coordinated and uniform nature of Purdue's marketing, Purdue conveyed these deceptive messages to Nassau County prescribers. The materials that Purdue generated in collaboration with third parties also were distributed or made available in Nassau County. Purdue distributed these messages, or facilitated their distribution, in Nassau County with the intent that Nassau County prescribers and/or consumers would rely on them in choosing to use opioids to treat chronic pain.

[150] The FDA-approved labels for both Nucynta and Nucynta ER describe the tapentadol molecule as an "opioid agonist and a Schedule II controlled substance that can be abused in a manner similar to other opioid agonists, legal or illicit."

a. Purdue's Deceptive Direct Marketing

597. Like the other Defendants, Purdue directly disseminated deceptive branded and unbranded marketing focused on minimizing the risks associated with the long-term use of opioids to treat chronic pain. Purdue directed these messages to prescribers and consumers through its sales force and branded advertisements.

598. Purdue engaged in in-person marketing to doctors in Nassau County. Purdue had 250 sales representatives in 2007, of whom 150 were devoted to promoting sales of OxyContin full time. Like the other Defendants' detailers, Purdue sales representatives visited targeted physicians to deliver sales messages that were developed centrally and deployed, identically, across the country. These sales representatives were critical in delivering Purdue's marketing strategies and talking points to individual prescribers.[151] Indeed, Endo's internal documents indicate that pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed the AAPM/APS Guidelines, which as discussed above deceptively concluded that the risk of addiction is manageable for patients regardless of past abuse histories, with doctors during individual sales visits.

599. Purdue's spending on detailing reached its nadir in 2006 and 2007, as the company faced civil and criminal charges for misbranding OxyContin. Since settling those charges in 2007, however, Purdue has sharply increased its quarterly spending on promotion through its sales force, from under $5 million in 2007 to more than $30 million by the end of 2014.

600. Purdue also marketed its drugs through branded advertisements which relied on, among other deceptive tactics, misleading statements about the efficacy and onset of OxyContin. Purdue marketed its drug as effective for 12 hours while knowing that these claims were misleading

[151] But Purdue did not stop there. It also tracked around 1,800 doctors whose prescribing patterns demonstrated a probability that they were writing opioid prescriptions for addicts and drug dealers. Purdue kept the program secret for nine years and, when it finally did report information about these suspicious doctors to law enforcement authorities, it only did so with respect to 8% of them.

because, for many patients, the pain relief lasted for as little as eight hours, leading to end-of-dose failure and withdrawal symptoms. This prompted doctors to prescribe, or patients to take, higher or more frequent doses of opioids, all of which increased the risk of abuse and addiction.

601. For example, a "Conversion and Titration Guide" submitted to the FDA and distributed to physicians by Purdue, prominently referred to "Q12h OxyContin Tablets," meaning that each tablet was intended to "offer . . . every-twelve-hour dosing." Other marketing materials directed at physicians and disseminated across the country in 2006 touted that OxyContin's "12-hour AcroContin Delivery System" was "designed to deliver oxycodone over 12 hours," which offered patients "life with Q12H relief." Those same marketing materials included a timeline graphic with little white paper pill cups at "8AM" and, further down the line, at "8PM" only. They also proclaimed that OxyContin provided "Consistent Plasma Levels Over 12 Hours" and set forth charts demonstrating absorption measured on a logarithmic scale, which fraudulently made it appear that levels of oxycodone in the bloodstream slowly taper over a 12-hour time period.

602. Purdue advertisements that ran in 2005 and 2006 issues of the *Journal of Pain* depicted a sample prescription for OxyContin with "Q12h" handwritten. Another advertisement Purdue ran in 2005 in the *Journal of Pain* touted OxyContin's "Q12h dosing convenience" and displayed two paper dosing cups, one labeled "8 am" and one labeled "8 pm," implying that OxyContin is effective for the 12-hour period between 8 a.m. and 8 p.m. Similar ads appeared in the March 2005 *Clinical Journal of Pain*.

603. Purdue continued to include prominent 12-hour dosing instructions in its branded advertising, such as in a 2012 Conversion and Titration Guide, which states: "Because each patient's treatment is personal / Individualize the dose / Q12h OxyContin Tablets."

604. As outlined above, however, these statements are misleading because they fail to make clear that a 12-hour dose does not equate to 12 hours of pain relief. Nevertheless, Purdue's direct marketing materials have misleadingly claimed OxyContin offers 12 hour "dosing convenience."

605. As described below, these deceptive statements regarding the efficacy of OxyContin were also carried into Nassau County by Purdue's detailers.

606. Purdue's direct marketing materials also misrepresented that opioids would help patients regain functionality and make it easier for them to conduct everyday tasks like walking, working, and exercising.

607. For example, in 2012, Purdue disseminated a mailer to doctors titled "Pain vignettes." These "vignettes" consisted of case studies describing patients with pain conditions that persisted over a span of several months. One such patient, "Paul," is described as a "54-year-old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work. None of these ads, however, disclosed the truth—that there is no evidence that opioids improve patients' lives and ability to function and that there was substantial evidence to the contrary.

608. Some of the greatest weapons in Purdue's arsenal, however, were unbranded materials it directly funded and authored. These were in addition to the unbranded materials, described below, that Purdue channeled through third parties.

609. In 2011, Purdue published a prescriber and law enforcement education pamphlet titled *Providing Relief, Preventing Abuse*, which deceptively portrayed the signs—and therefore the prevalence—of addiction. However, Purdue knew, as described above, that OxyContin was used non-medically by injection less than less than 17% of the time. Yet, *Providing Relief, Preventing Abuse* prominently listed side effects of injection like skin popping and track marks as "Indications of Possible Drug Abuse"—downplaying much more prevalent signs of addiction associated with

OxyContin use such as asking for early refills, making it seem as if addiction only occurs when opioids are taken illicitly.

610. *Providing Relief, Preventing Abuse* also deceptively camouflaged the risk of addiction by falsely supporting the idea that drug-seeking behavior could, in fact, be a sign of "pseudoaddiction" rather than addiction itself. Specifically, it noted that the concept of "pseudoaddiction" had "emerged in the literature" to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated." Nowhere in *Providing Relief, Preventing Abuse* did Purdue disclose the lack of scientific evidence justifying the concept of "pseudoaddiction," or that the phrase itself had been coined by a Purdue vice president.

611. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach Nassau County prescribers. As described below, the deceptive statements in *Providing Relief, Preventing Abuse* regarding addiction were the very same messages Purdue directed at Nassau County prescribers through its sales force.

612. Purdue also disseminated misrepresentations through two of its unbranded websites, *In the Face of Pain* and *Partners Against Pain*.

613. Consistent with Purdue's efforts to portray opioid treatment as "essential" for the proper treatment of chronic pain and label skepticism related to chronic opioid therapy as an "inadequate understanding" that leads to "inadequate pain control," *In the Face of Pain* criticized policies that limited access to opioids as being "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. This was meant to imply that patients should keep looking until they find a doctor willing to prescribe opioids.

614. *In the Face of Pain* was available nationally and was intended to reach Nassau County prescribers.

615. Purdue also used its unbranded website *Partners Against Pain* to promote the same deceptive messages regarding risk of addiction and delivered by its sales representatives. On this website, Purdue posted *Clinical Issues in Opioid Prescribing*, a pamphlet that was copyrighted in 2005. Purdue also distributed a hard-copy version of this pamphlet. *Clinical Issues in Opioid Prescribing* claimed that "illicit drug use and deception" were not indicia of addiction, but rather indications that a patient's pain was undertreated. The publication indicated that "[p]seudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated." In other words, Purdue suggested that when faced with drug-seeking behavior from their patients, doctors should prescribe more opioids—turning evidence of addiction into an excuse to sell and prescribe even more drugs.

616. Purdue's misleading messages and materials were part of a broader strategy to convince prescribers to use opioids to treat their patients' pain, irrespective of the risks, benefits, and alternatives. This deception was national in scope and included Nassau County. As described above, Purdue's nationwide messages would have reached County prescribers in a number of ways. For example, they were carried into Nassau County by Purdue's sales representatives during detailing visits as well as made available to Nassau County patients and prescribers through websites and ads, including ads in prominent medical journals. They would have also been delivered to Nassau County prescribers by Purdue's paid speakers, who were required by Purdue policy and by FDA regulations to stay true to Purdue's nationwide messaging.

b. Purdue's Deceptive Third-Party Statements

617. Purdue's efforts were not limited to making misrepresentations through its own sales force and its own branded and unbranded marketing materials. As described above, Purdue knew that regulatory constraints restricted what it could say about its drugs through direct marketing. For this

reason, like the other Defendants, Purdue enlisted the help of third parties to release misleading information about opioids. The most prominent of these was APF.

i. *APF*

a) Purdue's Control of APF

618. Purdue exercised considerable control over APF, which published and disseminated many of the most blatant falsehoods regarding chronic opioid therapy. Their relationship, and several of the APF publications, is described in detail below.

619. Purdue exercised its dominance over APF over many projects and years. Purdue was APF's second-biggest donor, with donations totaling $1.7 million. Purdue informed APF that the grant money reflected Purdue's effort to "strategically align its investments in nonprofit organizations that share [its] business interests," making clear that Purdue's funding depended upon APF continuing to support Purdue's business interests. Indeed, Purdue personnel participated in a March 2011 call with APF's "Corporate Roundtable," where they suggested that APF "[s]end ambassadors to talk about pain within companies and hospitals." Thus, Purdue suggested what role APF could play that would complement its own marketing efforts. On that call, Purdue personnel also committed to provide APF with a list of "industry state advocates" who could help promote chronic opioid therapy, individuals and groups that, upon information and belief, APF reached out to. Purdue personnel remained in constant contact with their counterparts at APF.

620. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF

was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. This agreement demonstrates APF's lack of independence and its willingness to surrender to Purdue's control and commercial interests, which would have carried across all of APF's work.

621. Purdue used this agreement to conduct work with APF on the *Partners Against Pain* website. *Partners Against Pain* is a Purdue-branded site, and Purdue holds the copyright.

622. However, its ability to deploy APF on this project illustrates the degree of control Purdue exercised over APF. In 2011, it hired an APF employee to consult on the *Partners Against Pain* rollout, to orchestrate the media campaign associated with the launch of certain content on the website, and to make public appearances promoting the website along with a celebrity spokesperson. Purdue contemplated paying this consultant $7,500 in fees and expenses for 26 hours of work. Purdue would require this consultant to "to discuss and rehearse the delivery of [Purdue's] campaign messages" and Purdue committed that "[m]essage points will be provided to [the] Consultant in advance and discussed on [a planned] call." At all times, decisions regarding the final content on the *Partners Against Pain* website were "at the sole discretion of Purdue."

623. APF also volunteered to supply one of its staff (a medical doctor or a nurse practitioner) to assist Purdue as a consultant and spokesperson for the launch of one of Purdue's opioid-related projects, *Understanding & Coping with Lower Back Pain*, which appeared on *Partners Against Pain*. One of the consultants was APF's paid employee, Mickie Brown. The consultant's services would be provided in return for a $10,000 consulting fee for APF and $1,500 in honoraria for the spokesperson. All documents used by the consultant in her media appearances would be reviewed and approved by individuals working for Purdue. It was not until later that APF worried about "how Purdue sees this program fitting in with our [existing] grant request."

624. Given the financial and reputational incentives associated with assisting Purdue in this project and the direct contractual relationship and editorial oversight, APF personnel were acting under Purdue's control at all relevant times with respect to *Partners Against Pain*.

625. APF acquiesced to Purdue's frequent requests that APF provide "patient representatives" for *Partners against Pain*. Moreover, APF staff and board members and Front Groups ACPA and AAPM, among others (such as Dr. Webster), appear on *Inthefaceofpain.com* as "Voices of Hope"—"champions passionate about making a difference in the lives of people who live with pain" and providing "inspiration and encouragement" to pain patients. APF also contracted with Purdue for a project on back pain in which, among other things, it provided a patient representative who agreed to attend a Purdue-run "media training session."

626. According to an Assurance of Voluntary Compliance ("AVC") entered into between the New York Attorney General and Purdue Pharma on August 19, 2015, *Inthefaceofpain.com* received 251,648 page views between March 2014 and March 2015. With the exception of one document linked to the website, *Inthefaceofpain.com* makes no mention of opioid abuse or addiction. Purdue's copyright appears at the bottom of each page of the website, indicating its ownership and control of its content. There is no other indication that 11 of the individuals who provided testimonials on *Inthefaceofpain.com* received payments, according to the AVC, of $231,000 for their participation in speakers programs, advisory meetings and travel costs between 2008 and 2013. The New York Attorney General found Purdue's failure to disclose its financial connections with these individuals had the potential to mislead consumers.

627. Nowhere was Purdue's influence over APF so pronounced as it was with the APF's "Pain Care Forum" ("PCF"). PCF was and continues to be run not by APF, but by Defendant Purdue's in-house lobbyist, Burt Rosen. As described by a former drug company employee, Rosen exercised full control of PCF, telling them "what do do and how to do it." This control allowed him,

in turn, to run APF as, in accordance with Rosen's thinking, "PCF was APF, which was Purdue." PCF meets regularly in-person and via teleconference, and shares information through an email listserv.

628. In 2011, APF and another third-party advocacy group, the Center for Practical Bioethics, were considering working together on a project. Having reviewed a draft document provided by the Center for Practical Bioethics, the APF employee cautioned that "this effort will be in cooperation with the efforts of the PCF" and acknowledged that "I know you have reservations about the PCF and pharma involvement, but I do believe working with them and keeping the lines of communications open is important." The Center for Practical Bioethics CEO responded by indicating some confusion about whom to speak with, asking "[i]s Burt Rosen the official leader" and reflecting what other sources have confirmed.

629. In 2007, the PCF Education Subgroup, consisting of drug companies Purdue and Alpharma, and Front Groups APF and ACPA (self-described as "industry-funded" groups), developed a plan to address a perceived "lack of coordination" among the industry and pro-opioid professional and patient organizations. PCF members agreed to develop simplified "key" messages" to use for public education purposes. Their messages were reflected in programs like NIPC's *Let's Talk Pain* (put together by Endo and APF), and Purdue's *In the Face of Pain*.

630. When the FDA required drug companies to fund CMEs related to opioid risks in accordance with its 2009 REMS, Purdue, along with these Front Groups, worked through the PCF to ensure that, although it was mandatory for drug companies to fund these CMEs, it would not be mandatory for prescribers to attend them. A survey was circulated among Defendants Endo, Janssen, and Purdue, which predicted that the rates of doctors who would prescribe opioids for chronic pain would fall by 13% if more than four hours of mandatory patient education were required in

accordance with the REMS. With a push from PCF, acting under Purdue's direction, the CMEs were not made mandatory for prescribers.

631. APF showed its indebtedness to Purdue and its willingness to serve Purdue's corporate agenda when APF chairman Dr. James N. Campbell testifyied on the company's behalf at a July 2007 hearing before the Senate Judiciary Committee "evaluating the propriety and adequacy of the OxyContin criminal settlement."[152] Despite its ostensible role as a patient advocacy organization, APF was willing to overlook substantial evidence—resulting in the jailing of Purdue executives—that Purdue blatantly, despite its clear knowledge to the contrary, told physicians and patients that OxyContin was "rarely" addictive and less addictive than other opioids. Like Purdue, APF ignored the truth about opioids and parroted Purdue's deceptive messaging. Dr. Campbell testified on Purdue's behalf that addiction was a "rare problem" for chronic pain patients and asserted: "[T]he scientific evidence suggests that addiction to opioids prescribed by legitimate chronic non-cancer pain patients without prior histories of substance abuse using the medication as directed is rare. Furthermore, no causal effect has been demonstrated between the marketing of OxyContin and the abuse and diversion of the drug." There was, and is, no scientific support for those statements.

632. APF President Will Rowe reached out to Defendants—including Purdue—rather than his own staff, to identify potential authors to answer a 2011 article critical of opioids that had been published in the Archives of Internal Medicine..

[152] *Evaluating the Propriety and Adequacy of the Oxycontin Criminal Settlement: Before the S. Comm. On the Judiciary*, 110th Cong. 46-50, 110-116 (2007) (statements of Dr. James Campbell, Chairman, APF), https://www.judiciary.senate.gov/imo/media/doc/Campbell%20Testimony%20073107.pdf (accessed May 30, 2017). Purdue was also able to exert control over APF through its relationships with APF's leadership. Purdue-sponsored KOLs Russell Portenoy and Scott Fishman chaired APF's board. Another APF board member, Perry Fine, also received consulting fees from Purdue. APF board member Lisa Weiss was an employee of a public relations firm that worked for both Purdue and APF. Weiss, in her dual capacity, helped vet the content of the Purdue-sponsored *Policymaker's Guide*, which is described below.

633. Purdue's control over APF shaped, and was demonstrated by specific APF, pro-opioid publications. These publications had no basis in science and were driven (and can only be explained) by the commercial interest of pharmaceutical companies—Purdue chief among them.

b) *A Policymaker's Guide*

634. Purdue provided significant funding to and was involved with APF's creation and dissemination of *A Policymaker's Guide to Understanding Pain & Its Management*, originally published in 2011 and still available online. *A Policymaker's Guide to Understanding Pain & Its Management* misrepresented that there were studies showing that the use of opioids for the long-term treatment of chronic pain could improve patients' ability to function.

635. Specifically, *A Policymaker's Guide to Understanding Pain & Its Management* claimed that "multiple clinical studies" demonstrated that "opioids . . . are effective in improving [d]aily function, [p]sychological health [and] [o]verall health-related quality of life for people with chronic pain" and implied that these studies established that the use of opioids long-term led to functional improvement. The study cited in support of this claim specifically noted that there were no studies demonstrating the safety of opioids long-term and noted that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids."[153]

636. The *Policymaker's Guide* also misrepresented the risk of addiction. It claimed that pain had generally been "undertreated" due to "[m]isconceptions about opioid addiction" and that "less than 1% of children treated with opioids become addicted."

637. Moreover, the *Policymaker's Guide* attempted to distract doctors from their patients' drug-seeking behavior by labeling it as "pseudoaddiction," which, according to the guide, "describes patient behaviors that may occur when pain is undertreated." Like *Partners Against Pain*, *A*

[153] Andrea D. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006).

Policymaker's Guide noted that "[p]seudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." The similarity between these messages regarding "pseudoaddiction" highlights the common, concerted effort behind Purdue's deceptive statements.

638. The *Policymaker's Guide* further misrepresented the safety of increasing doses of opioids and deceptively minimized the risk of withdrawal. For example, the *Policymaker's Guide* claimed that "[s]ymptoms of physical dependence" on opioids in long-term patients "can often be ameliorated by gradually decreasing the dose of medication during discontinuation" while omitting the significant hardship that often accompanies cessation of use. Similarly, the *Policymaker's Guide* taught that even indefinite dose escalations are "sometimes necessary" to reach adequate levels of pain relief while completely omitting the safety risks associated with increased doses.

639. Purdue provided substantial monetary assistance toward the creation and dissemination of the *Policymaker's Guide*, providing APF with $26,000 in grant money. APF ultimately disseminated *Policymaker's Guide* on behalf of Defendants, including Purdue. Purdue was not only kept abreast of the content of the guide as it was being developed, but, based on the periodic reports APF provided to Purdue regarding its progress on the *Policymaker's Guide*, had editorial input of the contents.

640. The *Policymaker's Guide* was posted online and was available to, and intended to reach Nassau County prescribers and consumers. As described below, the deceptive statements in *Policymaker's Guide* regarding addiction and functionality were the very same messages Purdue directed at Nassau County through its own sales force.

c) *Treatment Options: A Guide for People Living with Pain*

641. Purdue's partnership with APF did not end with the *Policymaker's Guide*. Purdue also substantially assisted APF by sponsoring *Treatment Options: A Guide for People Living with Pain*, starting in 2007. Based on Purdue's control of other APF projects, Purdue also would have exercised control over *Treatment Options*.

642. *Treatment Options* is rife with misrepresentations regarding the safety and efficacy of opioids. For example, *Treatment Options* misrepresents that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when used properly, opioids "give [pain patients] a quality of life [they] deserve."

643. Further, as outlined above, *Treatment Options* claims that addiction is rare and that, when it does occur, it involves unauthorized dose escalations, patients who receive opioids from multiple doctors, or theft, painting a narrow and misleading portrait of opioid addiction.

644. *Treatment Options* also promotes the use of opioids to treat long-term chronic pain by denigrating alternate treatments, most particularly NSAIDs. *Treatment Options* notes that NSAIDs can be dangerous at high doses and inflates the number of deaths associated with NSAID use, distinguishing opioids as having less risk. According to *Treatment Options*, NSAIDs are different from opioids because opioids have "no ceiling dose." This lack of ceiling is considered to be beneficial as some patients "need" larger doses of painkillers than they are currently prescribed. *Treatment Options* warns that the risks associated with NSAID use increased if NSAIDs are "taken for more than a period of months," but deceptively omits any similar warning about the risks associated with the long-term use of opioids.

645. *Treatment Options* was posted online and remains online today. It was available to and intended to reach Nassau County prescribers and patients. As described below, the deceptive statements in *Treatment Options* regarding addiction and functionality echo the messages Purdue directed at Nassau County through its own sales force. Purdue also engaged in other promotional projects with and through APF. One such project was the publication and distribution of *Exit Wounds*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain.

646. Purdue provided APF with substantial assistance in distributing *Exit Wounds* in Nassau County and throughout the nation by providing grant money and other resources.

ii. *Purdue's Work with Other Third Party Front Groups and KOLs*

647. Purdue also provided other third-party Front Groups with substantial assistance in issuing misleading statements regarding the risks, benefits, and superiority of opioids for the long-term treatment of chronic pain.

a) FSMB – *Responsible Opioid Prescribing*

648. In 2007, Purdue sponsored FSMB's *Responsible Opioid Prescribing*, which, as described above, deceptively portrayed the risks, benefits, and superiority of opioids to treat chronic pain. *Responsible Opioid Prescribing* also was drafted by Dr. Scott Fishman.

649. Purdue spent $150,000 to help FSMB distribute *Responsible Opioid Prescribing*. The book was distributed nationally, and was available to and intended to reach prescribers in Nassau County.

b) AGS – *Pharmacological Management of Persistent Pain in Older Persons*

650. Along with Janssen, Purdue worked with the AGS on a CME to promote the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. As discussed above, these guidelines falsely claimed that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse" as the study supporting this assertion did not analyze addiction rates by age. They also stated, falsely, that "[a]ll patients with moderate to severe pain should be considered for opioid therapy (low quality of evidence, strong recommendation)."

651. Controversy surrounding earlier versions of AGS guidelines had taught AGS that accepting money directly from drug companies to fund the guidelines' development could lead to allegations of bias and "the appearance of conflict." Accordingly, AGS endeavored to eliminate "the root cause of that flack" by turning down commercial support to produce the 2009 Guidelines. Having determined that its veneer of independence would be tarnished if it accepted drug company

money to create the content, AGS decided to develop the guidelines itself and turn to the drug companies for funding to *distribute* the pro-drug company content once it had been created. As explained by AGS personnel, it was AGS's "strategy that we will take commercial support to disseminate [the 2009 Guidelines] if such support is forthcoming." AGS knew that it would be difficult to find such support unless the report was viewed favorably by opioid makers.

652. AGS sought and obtained grants from Endo and Purdue to distribute *Pharmacological Management of Persistent Pain in Older Persons*. As a result, the publication was distributed nationally, and was available to and was intended to reach Nassau County prescribers. Indeed, internal documents of another Defendant, Endo, indicate that pharmaceutical sales representatives employed by Purdue discussed treatment guidelines that minimized the risk of addiction to opioids with doctors during individual sales visits.[154]

c) *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*

653. Purdue sponsored a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids. This CME was presented at various locations in the United States and is available online today.

d) *Managing Patient's Opioid Use: Balancing the Need and Risk*

654. Purdue also sponsored a 2011 CME taught by KOL Lynn Webster via webinar titled *Managing Patient's Opioid Use: Balancing the Need and Risk*. This presentation also deceptively instructed prescribers that screening tools, patient agreements, and urine test prevented "overuse of

[154] As described above, Purdue also provided substantial support for the AAPM/APS guidelines. The 1997 AAPM and APS consensus statement *The Use of Opioids for the Treatment of Chronic Pain* was authored by one of its paid speakers, and 14 out of 21 panel members who drafted the AAPM/APS Guidelines received support from Defendants Janssen, Cephalon, Endo, and Purdue.

prescriptions" and "overdose deaths." At the time, Dr. Webster was receiving significant funding from Purdue. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Purdue (and other Defendants). The webinar was available to and was intended to reach Nassau County prescribers.

e) *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*

655. Purdue also sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. *Path of the Patient* was devoted entirely to the message of treating chronic pain with opioids. Although the program purported to instruct a treating physician how to manage chronic pain in younger adults at risk for abuse, it does no such thing.

656. This "educational" program, addressing treatment of a population known to be particularly susceptible to opioid addiction, presents none of the alternative treatment options available, only discussing treatment of chronic pain with opioids.

657. In a role-play in *Path of the Patient*, a patient who suffers from back pain tells his doctor that he is taking twice as many hydrocodone pills as directed. The doctor reports that the pharmacy called him because of the patient's early refills. The patient has a history of drug and alcohol abuse. Despite these facts, the narrator notes that, because of a condition known as "pseudoaddiction," the doctor should not assume his patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor in the role-play treats this patient by prescribing a high-dose, long-acting opioid. This CME was available online and was intended to reach County prescribers.

f) *Overview of Management Options*

658. Purdue also sponsored a CME titled *Overview of Management Options* issued by the American Medical Association in 2003, 2007, and 2013 (the latter of which is still available for CME credit). The CME was edited by KOL Russel Portenoy, among others. It deceptively instructs physicians that NSAIDs and other drugs, but not opioids, are unsafe at high doses. In reality, the data indicates that patients on high doses of opioids are more likely to experience adverse outcomes than patients on lower doses of the drugs. Dr. Portenoy received research support, consulting fees, and honoraria from Purdue (among others), and was a paid Purdue consultant. This CME was presented online in the United States and was available to Nassau County prescribers.

iii. *Purdue's Misleading Science*

659. Purdue also misrepresented the risks associated with long-term opioid use by promoting scientific studies in a deceptive way. In 1998, Purdue funded two articles by Dr. Lawrence Robbins, which showed that between 8% and 13% of the patients he studied became addicted to opioids—a troubling statistic for Purdue, whose market, and marketing, depended upon the claim that opioids were rarely addictive.[155] Purdue had these articles placed in headache-specific journals where they would be less likely to be encountered by pain specialists or general practitioners. The first of these articles has been cited a mere 16 times; the second does not even appear on Google scholar. Five years later, Purdue funded a study of OxyContin in diabetic neuropathy patients, which was published in 2003. Notwithstanding the fact that that Purdue-funded studies, testing Purdue's own drugs, had previously indicated that addiction rates were between 8% and 13%, Purdue's 2003 article reached back to the 1980 Porter-Jick Letter to support its claim that OxyContin was not commonly

[155] Lawrence Robbins, *Long-Acting Opioids for Severe Chronic Daily Headache*, 10(2) Headache Q. 135 (1999); Lawrence Robbins, *Works in Progress: Oxycodone CR, a Long-Acting Opioid, for Severe Chronic Daily Headache*, 19 Headache Q. 305 (1999).

addictive. This article was placed in a prominent pain journal and has been cited 487 times.[156] While this article was drafted over a decade ago, it continues to be relied upon to further the misrepresentations that opioids are not addictive.

a) Purdue's Deceptive Statements to Nassau County Prescribers and Patients

660. Purdue directed the dissemination of the misstatements described above to Nassau County patients and prescribers through the Front Groups, KOLs, and publications described above, as well as through its sales force in Nassau County and through advertisements in prominent medical journals. The deceptive statements distributed through each of these channels reflect a common theme of misrepresenting the benefits of Purdue's opioids, unfairly portraying the risks of addiction associated with their use, and deceptively implying that they would improve patients' ability to function.

661. The deceptive message that OxyContin provided 12 hours of pain relief was not only available to, and intended to, reach Nassau County prescribers through nationally circulated advertising, but was also carried directly into the offices of Nassau County doctors by Purdue's sales representatives.

662. Likewise, the deceptive messages minimizing addiction were not only directed at Nassau County patients and prescribers through the publications circulated above, but were also disseminated directly by Purdue's sales force.

663. Purdue also used its sales force to disseminate misleading statements about the ability of opioids to improve functionality.

664. Purdue's national marketing campaign included the misrepresentations described above and the company disseminated these same misrepresentations to Nassau County prescribers and

[156] C. Peter N. Watson et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial I painful diabetic neuropathy*, 105 Pain 71 (2003).

consumers. In particular, these prescriber accounts reflect that Purdue detailers omitted or minimized the risk of opioid addiction; claimed that Purdue's drugs would be less problematic for patients because they had extended release mechanisms, were tamper proof, and were "steady state"; claimed that OxyContin would provide 12 hours of pain relief; represented that screening tools could help manage the risk of addiction; minimized the symptoms of withdrawal; claimed or implied that opioids were safer than NSAIDs; and overstated the benefits of opioids, including by making claims of improved function.

665. A survey of a sample of physicians, who reported the messages that they retained from detailing visits and other promotional activity, documented that Purdue sales representatives from at least between 2008 and 2012, promoted OxyContin as being effective for a full 12 hours. Purdue sales representatives also promoted OxyContin as improving patients' sleep (an unsubstantiated functional improvement) to an orthopedic surgeon in 2006 and to a physicians' assistant in 2013. Purdue sales representatives also told internists that the reformulation of OxyContin prevented illegal drug use and that the formulation was 'less addicting," rather than being harder to adulterate. In 2011, Purdue sales representatives also claimed that the sustained-release property of OxyContin reduced patient "buzz," which is neither based on scientific evidence nor true.

666. The same survey indicated that Purdue sales representatives promoted its Schedule III opioid Butrans as having low or little abuse potential.

F. The Result of Defendants' Fraudulent Scheme

667. Through their direct promotional efforts, along with those of the third-party Front Groups and KOLs they assisted and controlled, and whose seemingly objective materials they distributed, Defendants accomplished exactly what they set out to do: change the institutional and public perception of the risk-benefit assessments and standard of care for treating patients with

chronic pain. As a result, Nassau County doctors began prescribing opioids long-term to treat chronic pain—something most would never have considered prior to Defendants' campaign.

668. But for the misleading information disseminated by Defendants, doctors would not, in most instances, have prescribed opioids as medically necessary or reasonably required to address chronic pain.

1. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Nassau County.

669. In the first instance, the County was damaged directly, through its payments of false claims for chronic opioid therapy by (a) partially funding a medical insurance plan for its employees and (b) its workers' compensation program.

670. Defendants' marketing of opioids caused health care providers to prescribe, and the County, through partially funding a medical insurance plan for its employees and its workers' compensation program, to pay for prescriptions of opioids to treat chronic pain. Because of Defendants' unbranded marketing, health care providers wrote and the County paid for prescriptions of opioids for chronic pain that were filled not only with their drugs, but with opioids sold by other manufacturers. All of these prescriptions were caused by Defendants' fraudulent marketing and therefore all of them constitute false claims. Because, as laid out below, the County is obligated to cover medically necessary and reasonably required care, it had no choice but to pay for these false and fraudulent claims.

671. The fact that the County would pay for these ineligible prescriptions was both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme. Defendants set out to change the medical and general consensus supporting chronic opioid therapy with the intention of encouraging doctors to prescribe, and government payors such as Nassau County, to pay for long-term prescriptions of opioids to treat chronic pain despite the absence of genuine evidence

supporting chronic opioid therapy and the contrary evidence regarding the significant risks and limited benefits from long-term use of opioids.

a. Increase in Opioid Prescribing Nationally

672. Defendants' scheme to change the medical consensus regarding opioid therapy for chronic pain was greatly successful. During the year 2000, outpatient retail pharmacies filled 174 million prescriptions for opioids nationwide, rising to 257 million in 2009.[157]

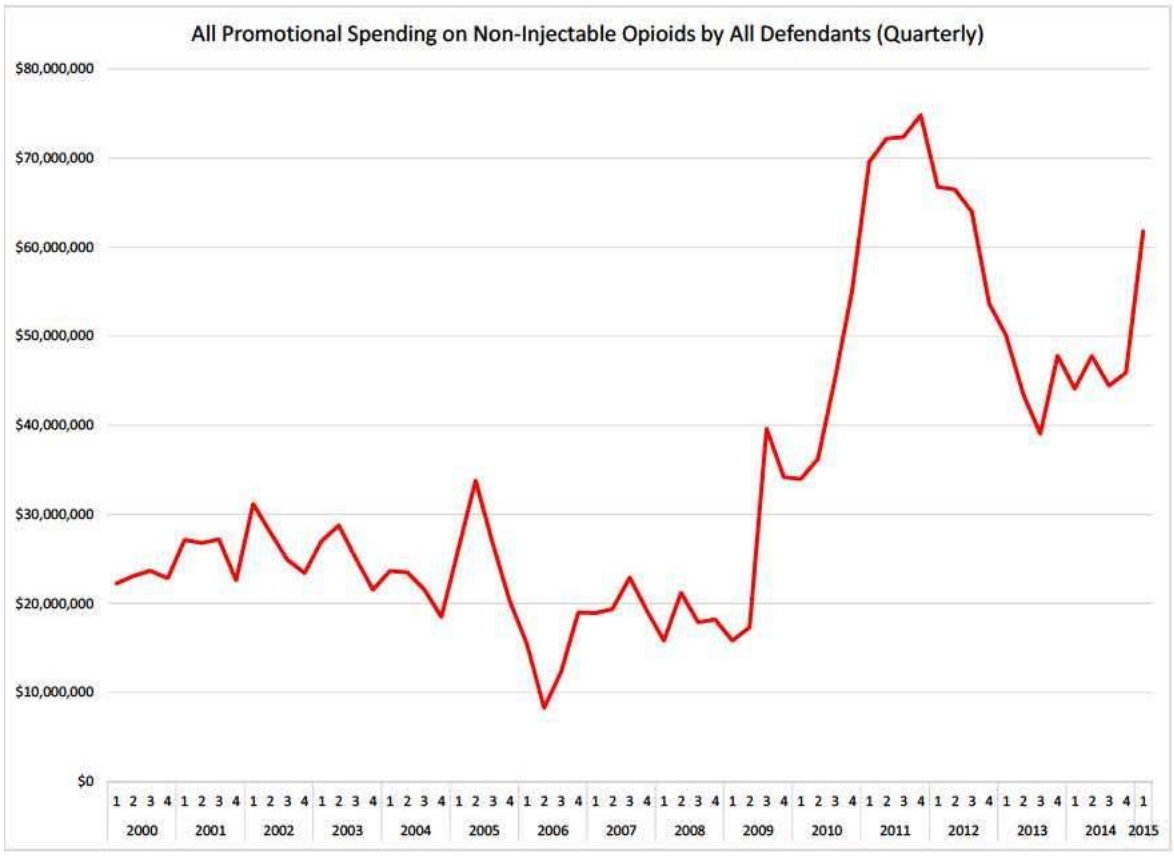
673. Opioid prescriptions increased even as the percentage of patients visiting doctors for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline of NSAID use.[158]

674. Approximately 20% of the population between the ages of 30 and 44 and nearly 30% of the population over 45 have used opioids. Indeed, "[o]pioids are the most common means of treatment for chronic pain."[159] From 1980 to 2000, opioid prescriptions for chronic pain visits doubled. This resulted not from an epidemic of pain, but an epidemic of prescribing. A study of 7.8 million doctor visits found that prescribing for pain increased by 73% between 2000 and 2010—even though the number of office visits in which patients complained of pain did not change and prescribing of non-opioid pain medications ***decreased***. For back pain alone—one of the most common chronic pain conditions—the percentage of patients prescribed opioids increased from 19% to 29% between 1999 and 2010, even as the use of NSAIDs or acetaminophen declined and referrals to physical therapy remained steady—and climbing.

---

[157] Office of National Drug Control Policy, *2011 Prescription Drug Abuse Prevention Plan*, Whitehouse.gov, (no longer available on whitehouse.gov), https://obamawhitehouse.archives.gov/ondcp/prescription-drug-abuse1 (accessed May 30, 2017).
[158] Matthew Daubresse et al., *Ambulatory* Diagnosis *and Treatment of Nonmalignant Pain in the United States, 2000-2010*, 51(10) Med. Care 870 (2013).
[159] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Arch. Intern. Med. 1426 (2011).

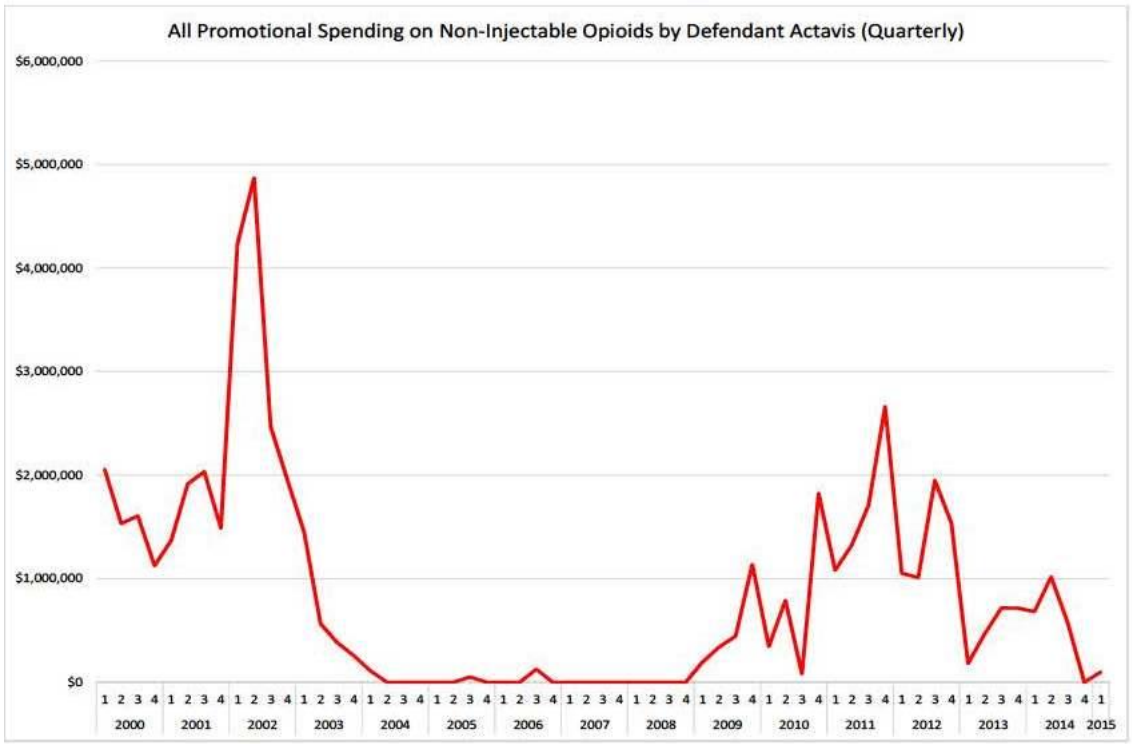
675. This increase corresponds with, and was caused by, Defendants' massive marketing push. As reflected in the chart below, according to data obtained from a marketing research company, Defendants' spending on marketing of opioids nationwide—including all of the drugs at issue here—stood at more than $20 million per quarter and $91 million annually in 2000. By 2011, that figure hit its peak of more than $70 million per quarter and $288 million annually, an increase of more than three-fold. By 2014, the figures dropped to roughly $45 million per quarter and $182 million annually, as Defendants confronted increasing concerns regarding opioid addiction, abuse, and diversion, and as Janssen, which accounted for most of the spending reduction, prepared to sell its U.S. rights to Nucynta and Nucynta ER. Even so, Defendants still spent double what they spent in 2000 on opioid marketing.



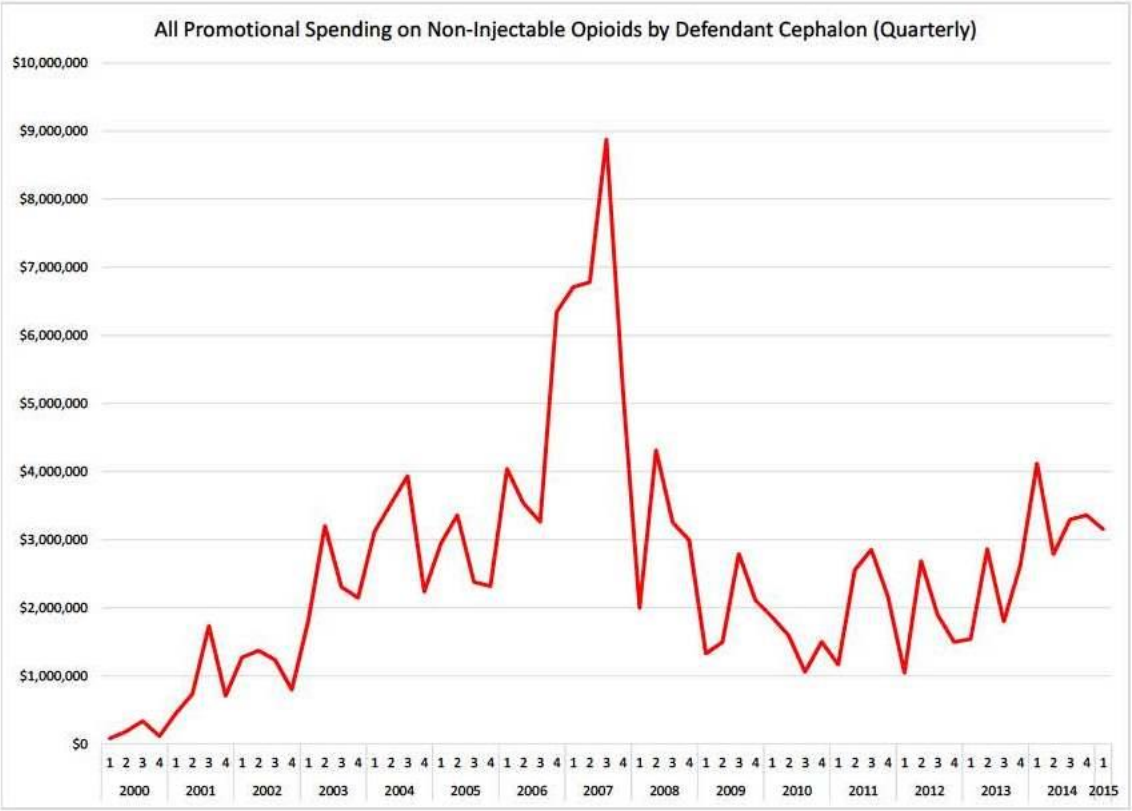
676. Defendants' opioid detailing visits to individual doctors made up the largest component of this spending, with total detailing expenditures more than doubling between 2000 and 2014 to $168 million annually.

677. Each Defendant's promotional spending reflects its participation in this marketing blitz. Between 2000 and 2011:

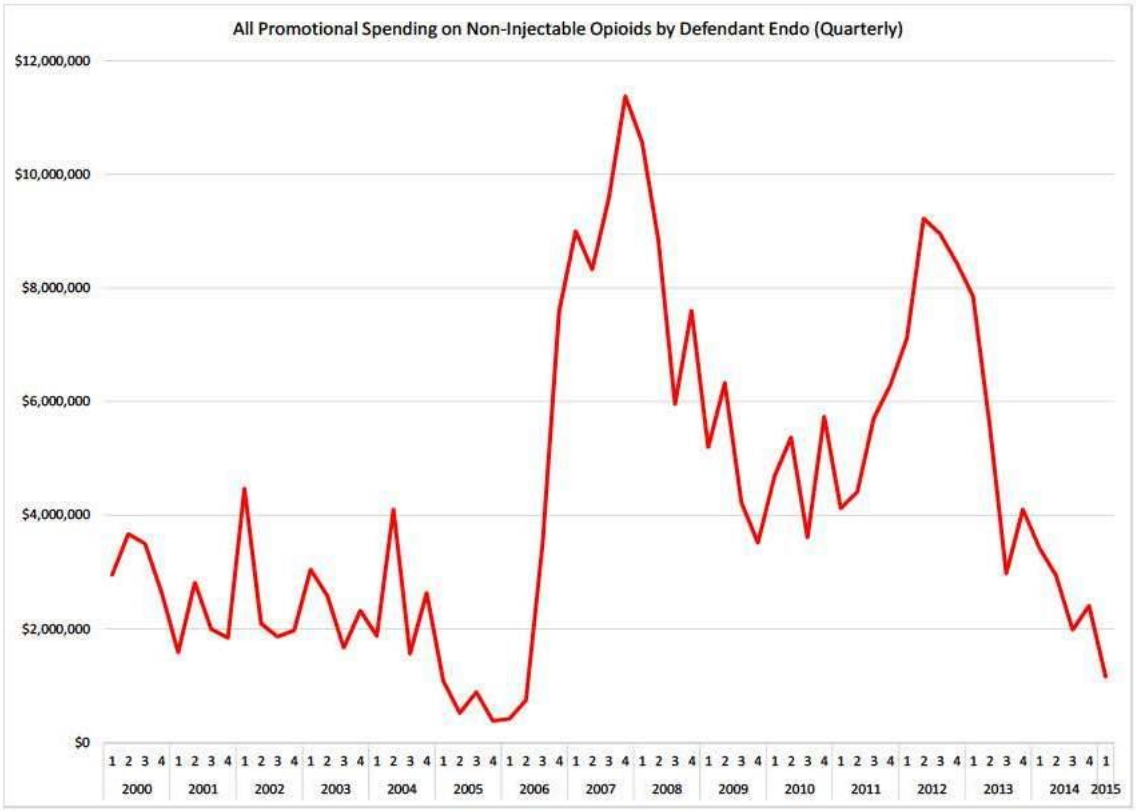
- Actavis's promotional spending, which was virtually nonexistent in the 2004-2008 period, began to sharply rise 2009. The third quarter of 2011 saw a peak of $3 million at one point in 2011 and nearly $7 million for the year, as shown below:



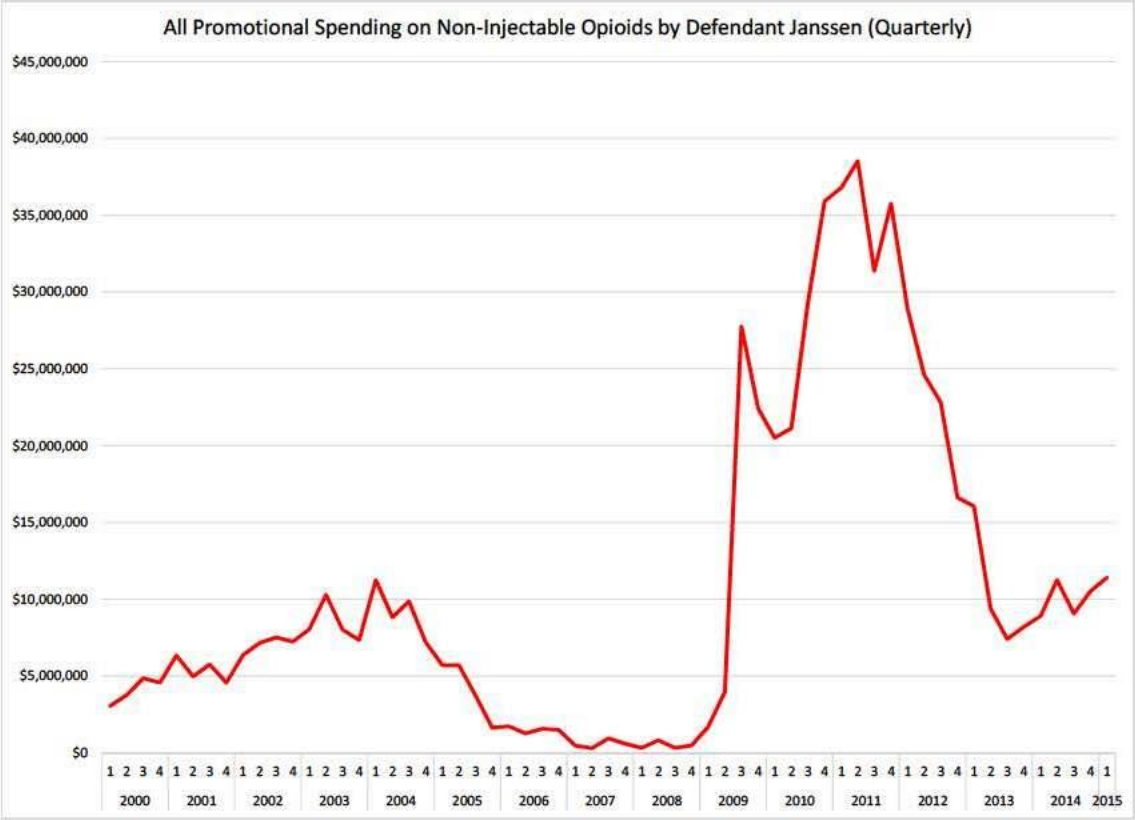
- Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $4 million in 2014 (and more than $13 million for the year), including a peak, coinciding with the launch of Fentora, of nearly $9 million half way through 2007 (and more than $27 million for the year), as shown below:



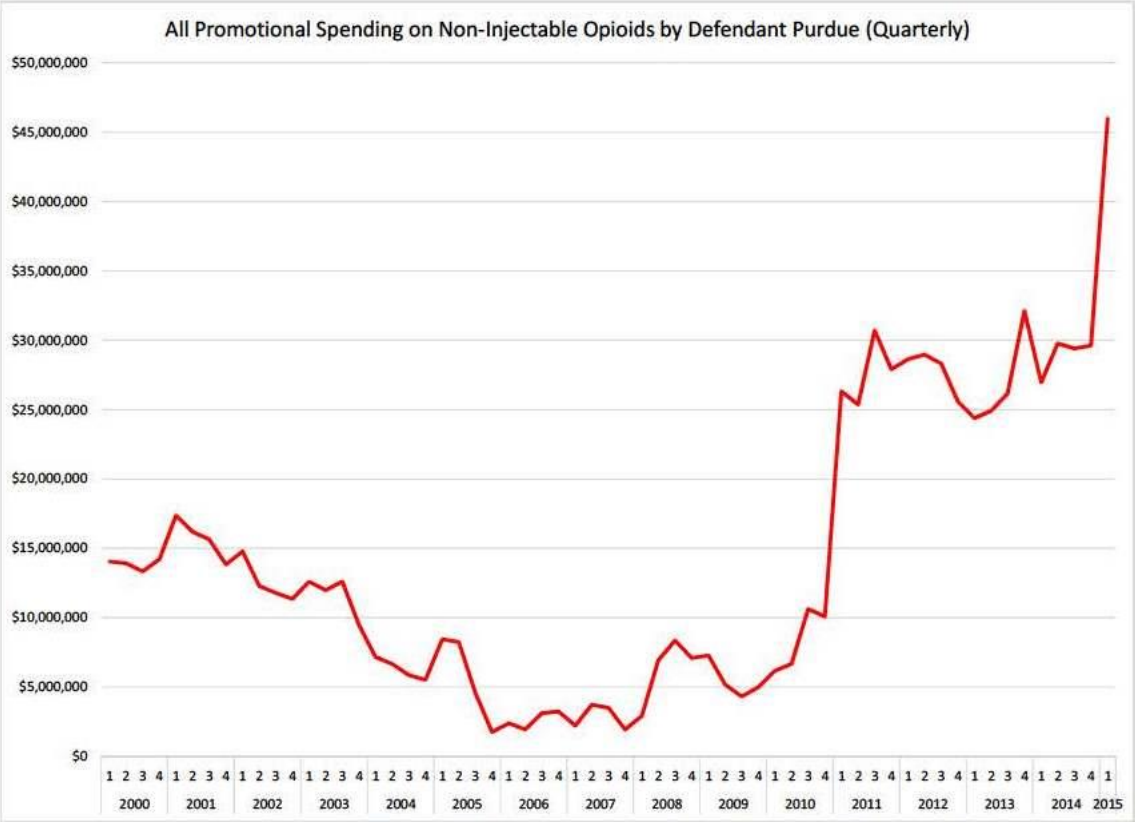
- Endo 's quarterly spending went from the $2 million to $4 million range from 2000 to 2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



- Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011) as shown below:



- Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continued to rise, as shown below:



b. The County's Increased Spending on Opioids

678. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has been required to spend millions of dollars each year in its efforts to combat the public nuisance created by Defendants' deceptive marketing campaign. Plaintiff has incurred, and continues to incur, costs related to opioid addiction and abuse, including, but not limited to, health care costs, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents.

i. *Defendants' Misrepresentations Were Material*

679. Defendants' misrepresentations were material to, and influenced, the County's decisions to pay claims for opioids for chronic pain (and, therefore, to bear its consequential costs in treating overdose, addiction, and other side effects of opioid use). In the first instance, the County would not have been presented with, or paid, claims for opioids that would not have been written but for Defendants' fraudulent and deceptive marketing. Second, the County has demonstrated that Defendants' marketing is material by taking further steps to ensure that the opioids are only prescribed and covered when medically necessary or reasonably required.

680. As laid out above, Defendants' misrepresentations related to the County's requirement that medical treatments be medically necessary or reasonably required – a condition of payment for any medical treatment under the County's health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

681. It is the County's practice not to pay claims that are not medically necessary or reasonably required. However, the County would not have known whether a prescriber had made an informed judgment that a particular claim for opioids was medically necessary or reasonably required, or, conversely had acted under the influence of Defendants' fraudulent and deceptive marketing. It is not clear from the face of a claim whether: (1) the patient suffered from cancer or another terminal condition, for example, where long-term prescribing was medically necessary or appropriate; or (2) the prescriber was exposed to Defendants' marketing materials, treatment guidelines, or education

programs, or visited by a drug representative who engaged in affirmative misrepresentations or omissions, for example.

ii. *The County's Increased Costs Correlate with Defendants' Promotion*

682. The County's spending in connection with opioids rose along with Defendants' spending to promote opioids. That spending was directly impacted by opioid use (and its consequences in abuse, addiction, and overdose) in Nassau County.

683. It is also distressing (and a sign of further problems ahead) that the drop in opioid prescribing beginning in 2014 has been accompanied by a corresponding increase in Defendants' promotional spending, which is headed towards a new high, despite evidence of the grave toll that opioids are taking on law enforcement, public health, and individual lives.

2. Defendants' Fraudulent and Deceptive Marketing of Opioids Directly Caused Harm to Nassau County Consumers.

a. Increased Opioid Use Has Led to an Increase in Opioid Abuse, Addiction, and Death

684. Nationally, the sharp increase in opioid use has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death. Scientific evidence demonstrates a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and opioid abuse. "Deaths from opioid overdose have risen steadily since 1990 in parallel with increasing prescription of these drugs."[160] Prescription opioid use contributed to 16,917 overdose deaths nationally in 2011—more than twice as many deaths as heroin and cocaine combined; drug poisonings now exceed motor vehicle accidents as a cause of death. More Americans have died from opioid overdoses than from participation in the Vietnam War.

[160] Deborah Grady et al., *Opioids for Chronic Pain,* 171(16) Arch. Intern. Med. 1426 (2011).

685. Contrary to Defendants' misrepresentations, most of the illicit use stems from *prescribed* opioids; in 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. According to the CDC, the 80% of opioid patients who take low-dose opioids from a single prescriber (in other words, who are not illicit users or "doctor-shoppers") account for 20% of all prescription drug overdoses.

686. Death statistics represent only the tip of the iceberg. According to 2009 data, for every overdose death that year, there were nine abuse treatment admissions, 30 emergency department visits for opioid abuse or misuse, 118 people with abuse or addiction problems, and 795 non-medical users. Nationally, there were more than 488,000 emergency room admissions for opioids other than heroin in 2008 (up from almost 173,000 in 2004).

687. Emergency room visits tied to opioid use likewise have sharply increased in Nassau County.

688. Widespread opioid use and abuse in Nassau County are problems even when they do not result in injury or death. Opioid addiction is affecting residents of all ages, ethnicities, and socio-economic backgrounds in the County. Many addicts start with a legal opioid prescription—chronic back pain, fibromyalgia, or even dental pain—and do not realize they are addicted until they cannot stop taking the drugs.

689. These glaring omissions, described consistently by counselors and patients, mirror and confirm Defendants' drug representatives' own widespread practice, as described above, of omitting any discussion of addiction from their sales presentations to physicians or in their "educational" materials.

b. Increased Opioid Use Has Increased Costs Related to Addiction Treatment

690. Nassau County has opioid treatment programs, Substance Alternative Clinics, that provide a comprehensive treatment program for persons addicted to heroin or other opioids.

691. In addition to intense counseling, many treatment programs prescribe additional drugs to treat opioid addiction. Nationally, in 2012, nearly 8 billion prescriptions of the two drugs commonly used to treat opioid addiction—buprenorphine/naloxone and naltrexone—were written and paid for. Studies estimate the total medical and prescription costs of opioid addiction and diversion to public and private healthcare payors to be $72.5 billion.

c. Increased Opioid Use Has Fueled An Illegal Secondary Market for Narcotics and the Criminals Who Support It

692. Defendants' success in extending the market for opioids to new patients and chronic conditions has created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Defendants' scheme supplies both ends of the secondary market for opioids—producing both the inventory of narcotics to sell and the addicts to buy them. One researcher who has closely studied the public health consequences of opioids has found, not surprisingly, that a "substantial increase in the nonmedical use of opioids is a predictable adverse effect of substantial increases in the extent of prescriptive use."[161] It has been estimated that the majority of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

693. A significant black market in prescription opioids also has arisen, not only creating and supplying additional addicts, but fueling other criminal activities.

694. In addition, because heroin is cheaper than prescription painkillers, many prescription opioid addicts migrate to heroin. Self-reported heroin use nearly doubled between 2007 and 2012, from 373,000 to 669,000 individuals. In 2010, more than 3,000 people in the U.S. died from heroin overdoses, also nearly double the rate in 2006. Nearly 80% of those who used heroin in the past year had previously abused prescription opioids. Patients become addicted to opioids and then move on to heroin because these prescription drugs are roughly four times more expensive than heroin on

[161] G. Caleb Alexander et al., *Rethinking Opioid Prescribing to Protect Patient Safety and Public Health*, 308(18) JAMA 1865 (2012).

the street. In the words of one federal DEA official, "Who would have ever thought in this country it would be cheaper to buy heroin than pills . . . [t]hat is the reality we're facing."[162]

695. That reality holds true in Nassau County. According to addiction programs, a typical course sees addicts requesting more and more opioids from their doctors, who eventually cut them off. Many addicts then doctor-shop for additional prescriptions, and when that source runs out, turn to the streets to buy opioids illicitly. A significant number become heroin addicts. Addiction treatment programs, whose patient populations vary, reported rates of patients who had switched from prescription opioids to heroin ranging from half to 95%. Those addicts who do reach treatment centers often do so when their health, jobs, families and relationships reach the breaking point, or after turning to criminal activity such as prostitution and theft to sustain their addiction. Unfortunately, few are successful in getting and staying clean; repeated relapse is common.

3. Defendants' Fraudulent Marketing Has Led to Record Profits

696. While the use of opioids has taken an enormous toll on Nassau County and its residents, Defendants have gained blockbuster profits. In 2012, health care providers wrote 259 million prescriptions for opioid painkillers[163]—roughly one prescription per American adult. Opioids generated $8 billion in revenue for drug companies just in 2010.

697. Financial information—where available—indicates that Defendants each experienced a material increase in sales, revenue, and profits from the fraudulent, misleading, and unfair market activities laid out above. Purdue's OxyContin sales alone increased from $45 million in 1996 to $3.1 billion in 2010.

---

[162] Matt Pearce & Tina Susman, *Philip Seymour Hoffman's death calls attention to rise in heroin use*, L.A. Times, Feb. 3, 2014, http://articles.latimes.com/2014/feb/03/nation/la-na-heroin-surge-20140204 (accessed May 30, 2017).

[163] Press Release, Center for Disease Control, Opioid painkiller prescribing varies widely among states: Where you live makes a difference (July 1, 2014), https://www.cdc.gov/media/releases/2014/p0701-opioid-painkiller.html (accessed May 30, 2017).

4. Defendants Fraudulently Concealed Their Misrepresentations

698. At all times relevant to this Complaint, Defendants took steps to avoid detection of, and fraudulently conceal, their deceptive marketing and conspiratorial behavior.

699. First, and most prominently, Defendants disguised their own roles in the deceptive marketing of chronic opioid therapy by funding and working through patient advocacy and professional front organizations and KOLs. Defendants purposefully hid behind these individuals and organizations to avoid regulatory scrutiny and to prevent doctors and the public from discounting their messages.

700. While Defendants were listed as sponsors of many of the publications described in this Complaint, they never disclosed their role in shaping, editing, and exerting final approval over their content. Defendants exerted their considerable influence on these promotional and "educational" materials.

701. In addition to hiding their own role in generating the deceptive content, Defendants manipulated their promotional materials and the scientific literature to make it appear as if they were accurate, truthful, and supported by substantial scientific evidence. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions they did not actually support. The true lack of support for Defendants' deceptive messages was not apparent to the medical professionals who relied upon them in making treatment decisions, nor could they have been detected by the County.

702. Thus, while the opioid epidemic was evident, Defendants, in furtherance of their respective marketing strategies, intentionally concealed their own role in causing it. Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the existence of claims that the County now asserts. The County was not

alerted to the existence and scope of Defendants industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

703. Through their public statements, marketing, and advertising, Defendants' deceptions deprived the County of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

FIRST CAUSE OF ACTION

DECEPTIVE ACTS AND PRACTICES NEW YORK GENERAL BUSINESS LAW §349 (AGAINST ALL DEFENDANTS)

704. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

705. New York General Business Law § 349 declares unlawful any deceptive acts or practices in the conduct of any business, trade or or commerce or in the furnishing of any service in the state, and allows any person who has been injured by reason of any violation of that statute to bring an action to recover actual damages.

706. Defendants violated New York General Business Law § 349, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

707. Plaintiff and its residents have been injured by reason of Defendants' violation of § 349.

708. Plaintiff is entitled to recover its damages caused by the violation of New York General Business Law § 349 by the defendants in an amount to be determined at trial, plus attorneys' fees.

SECOND CAUSE OF ACTION

FALSE ADVERTISING
NEW YORK GENERAL BUSINESS LAW §350
(AGAINST ALL DEFENDANTS)

709. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

710. Defendants violated New York General Business Law § 350, because they engaged in false advertising in the conduct of a business, trade or commerce in this state.

711. Plaintiff and its residents have been injured by reason of Defendants' violation of § 350.

THIRD CAUSE OF ACTION

PUBLIC NUISANCE
(AGAINST ALL DEFENDANTS)

712. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

713. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of a considerable number of persons in Nassau County by their production, promotion, and marketing of opioids for use by residents of Nassau County.

714. Defendants conduct is unreasonable.

715. Defendants' conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peace, order and safety; it is ongoing, and it is producing permanent and long-lasting damage.

716. Defendants' conduct constitutes a public nuisance.

717. Defendants' conduct directly and proximately caused injury to Plaintiff and its residents.

718. Plaintiff and its residents suffered special injuries distinguishable from those suffered by the general public.

FOURTH CAUSE OF ACTION

VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-B (AGAINST ALL DEFENDANTS)

719. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

720. Defendants violated Social Services Law § 145-b, because they knowingly, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to Chapter 55 of the Social Services Law. Plaintiff is a "political subdivision" of the State of New York as that term is used in § 145- b (1) (b) and a "local social services district" as that term is used in § 145-b (2).

721. By reason of Defendants' violation of § 145-b, Plaintiff has been damaged.

FIFTH CAUSE OF ACTION

FRAUD (AGAINST ALL DEFENDANTS)

722. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

723. Defendants, individually and acting through their employees and agents, and in concert with each other, knowingly made material misrepresentations and omissions of facts to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

724. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

725. Defendants intended that Plaintiff and its residents would rely on their misrepresentations and omissions.

726. Plaintiff and its residents reasonably relied upon Defendants' misrepresentations and omissions.

727. In the alternate, the Defendants recklessly disregarded the falsity of their representations regarding opioids.

728. By reason of their reliance on Defendants' misrepresentations and omissions of material fact Plaintiff and its residents suffered actual pecuniary damage.

729. Defendants' conduct was willful, wanton, and malicious and was directed at the public generally.

SIXTH CAUSE OF ACTION

UNJUST ENRICHMENT
(AGAINST ALL DEFENDANTS)

730. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

731. Defendants acted willfully, wantonly, and with conscious disregard of the rights of the Plaintiff and its residents.

732. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by Plaintiff and its residents.

733. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary

and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

734. Defendants, through the wrongful conduct described above, have been unjustly enriched at the expense of Plaintiff.

735. In equity and good conscience, it would be unjust and inequitable to permit defendants to enrich themselves at the expense of the Plaintiff and its residents.

736. By reason of the foregoing, Defendants must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution to the Plaintiff.

SEVENTH CAUSE OF ACTION

NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

737. Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

738. Distributor Defendants have a duty to exercise reasonable care in the distribution of opioids.

739. Distributor Defendants breached this duty by failing to take any action to prevent or reduce the distribution of the opioids.

740. As a proximate result, Distributor Defendants and its agents have caused Nassau County to incur excessive costs related to diagnosis, treatment, and cure of addiction or risk of addiction to opioids, the County has borne the massive costs of these illnesses and conditions by having to provide necessary resources for care, treatment facilities, and law enforcement services for County Residents and using County resources in relation to opioid use and abuse.

741. Distributor Defendants were negligent in failing to monitor and guard against third-party misconduct and participated and enabled such misconduct.

742. Distributor Defendants were negligent in disclosing to Nassau County suspicious orders for opioids pursuant to Section 80.22 of the New York Codes, Rules and Regulations.

743. Distributor Defendants' acts and omissions imposed an unreasonable risk of harm to others separately and/or combined with the negligent and/or criminal acts of third parties.

744. Distributor Defendants are in a class of a limited number of parties that can legally distribute opioids, which places it in a position of great trust by the County.

745. The trust placed in Distributor Defendants by Nassau County through the license to distribute opioids in Nassau County creates a duty on behalf of Distributor Defendants to prevent diversion of the medications it supplies to illegal purposes.

746. A negligent and/or intentional violation of this trust poses distinctive and significant dangers to the County and its residents from the diversion of opioids for non-legitimate medical purposes and addiction to the same by consumers.

747. Distributor Defendants were negligent in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent and/or ameliorate such distinctive and significant dangers.

748. Distributor Defendants are required to exercise a high degree of care and diligence to prevent injury to the public from the diversion of opioids during distribution.

749. Distributor Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the transaction of its business.

750. Distributor Defendants are in exclusive control of the management of the opioids it distributed to pharmacies and drug stores in Nassau County.

751. Nassau County is without fault and the injuries to the County and its residents would not have occurred in the ordinary course of events had Distributor Defendants used due care commensurate to the dangers involved in the distribution of opioids.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants, jointly and severally, as to the FIRST, SECOND, THIRD, FOURTH, FIFTH, SIXTH, and SEVENTH Causes of Action, awarding Plaintiff in amounts that exceed the jurisdiction of all lower Courts:

i. compensatory damages in an amount sufficient to fairly and completely compensate Plaintiff for all damages;

ii. treble damages, penalties, and costs pursuant to Social Services Law §145-b;

iii. treble damages, penalties and costs pursuant to General Business Law §§349(h) and 350-3(3);

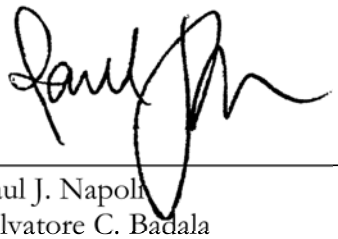
iv. Punitive Damages;

v. attorney's fees

vi. interest, Costs and Disbursements;

vii. such and further relief as this Court may deem just and proper.

Dated: June 12, 2017
Melville, New York



Paul J. Napoli
Salvatore C. Badala
Joseph L. Ciaccio
NAPOLI SHKOLNIK PLLC
400 Broadhollow Road, Suite 305
Melville, New York 11747

-and-

Carnell T. Foskey, County Attorney
Alpa J. Sanghvi, Deputy County Attorney
Nassau County Attorney's Office
1 West Street
Mineola, New York 11501
Attorneys for Plaintiff

City of Biddeford

IN BOARD OF CITY COUNCIL…JANUARY 2, 2018

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Bob Mills
10 Windsor Lane
Ward 4

to the *Cable T.V. Committee*, for a term to expire in December 2020.

CITY OF BIDDEFORD

Application for
City Committees, Commissions and Boards

Date: 12/11/17

Name: BOBBY MILLS

Street Address: 10 WINDSOR LANE

BIDDEFORD, ME 04005

Mailing Address: (if different) N/A

Phone Number(s): (207) 205-7917

Email Address: SPRINGRIDGE2004@YAHOO.COM

Which City Committee, Board or Commission do you request to be appointed to:

- ____ Airport Commission
- ____ Biddeford Fire Advisory Committee
- ____ Biddeford Housing Authority
- ____ Biddeford Police Advisory Committee
- ____ Board of Assessment Review
- ✓ Cable T.V. Committee
- ____ Capital Projects Committee
- ____ Conservation Commission
- ____ Downtown Development Commission
- ____ Economic Improvement Commission
- ____ Harbor Commission
- ____ Historic Preservation Commission
- ____ Planning Board
- ____ Policy Committee
- ____ Project Canopy Committee
- ____ Recreation Commission
- ____ Shellfish Conservation Committee
- ____ Solid Waste Management Commission
- ____ Wastewater Management Commission
- ____ Zoning Board of Appeals

571-0701

CITY OF BIDDEFORD
Committee Application

Please list any prior experience serving on any Public Boards, Commissions or Committees (and approximate dates)

CHARTER COMMISSION 2005
CITY COUNCIL 2007 - 2017, COUNCIL PRESIDENT 2009 - 2011
SCHOOL COMMITTEES SINCE 2007, FINANCE, CAPITAL PROJECTS, POLICY, WASTEWATER, OOC, AD-HOC COMMITTE'S, CABLE TV, ENVIRONMENTAL COMMISSION, ETC

Please list any other experience that may be pertinent to the Board or Committee in which you are requesting to serve on.

ZBA, WASTEWATER, BOARD OF ASSESSMENT REVIEW, CABLE TV COMMITTEE, TRANSIT

Please provide a brief statement describing your interest in serving the City of Biddeford.

I HAVE BEEN THE CHAIR OF CABLE T.V SINCE 2015. THE COMMITTEE HAS BEEN VERY ACTIVE IN KEEPING THE PUBLIC INVOLVED IN THE TIME WARNER AND SPECTRUM MERGER.

WE ARE STILL ACTIVELY IN RESOLVING CUSTOMER AND BUDGETARY ISSUES. ALSO WE ARE INVOLVED IN VOLUNTEER RECRUITMENT.

I WOULD LIKE TO STAY INVOLVED TO KEEP OUR PUBLIC SERVICE ACCESSIBLE AND USER FRIENDLY.

BC

Attach any additional information to this application and return it to the **City Clerk's** Office.

IN BOARD OF CITY COUNCIL…JANUARY 2, 2018

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Toni Sipka
115 Mile Stretch Road
Ward 1

to the *Cable T.V. Committee,* for a term to expire in December 2020.

CITY OF BIDDEFORD

Application for
City Committees, Commissions and Boards

Date: Dec. 11, 2017

Name: Toni SHIKA

Street Address: 115 MILE STRETCH RD
BIDDEFORD POOL, ME 04006

Mailing Address: P.O. Box 285
(if different) BIDDEFORD POOL, ME 04006

Phone Number(s): 207 571-7387

Email Address: ANNAKATONI@AOL.COM

Which City Committee, Board or Commission do you request to be appointed to:

- ____ • Airport Commission
- ____ • Biddeford Fire Advisory Committee
- ____ • Biddeford Housing Authority
- ____ • Biddeford Police Advisory Committee
- ____ • Board of Assessment Review
- X • Cable T.V. Committee
- ____ • Capital Projects Committee
- ____ • Conservation Commission
- ____ • Downtown Development Commission
- ____ • Economic Improvement Commission
- ____ • Harbor Commission
- ____ • Historic Preservation Commission
- ____ • Planning Board
- ____ • Policy Committee
- ____ • Project Canopy Committee
- ____ • Recreation Commission
- ____ • Shellfish Conservation Committee
- ____ • Solid Waste Management Commission
- ____ • Wastewater Management Commission
- ____ • Zoning Board of Appeals

CITY OF BIDDEFORD
Committee Application

Please list any prior experience serving on any Public Boards, Commissions or Committees (and approximate dates)

BIDDEFORD PTAC
BPIA
COMMUNITY CLUB
FUNCTIONS COMMITTEE

Please list any other experience that may be pertinent to the Board or Committee in which you are requesting to serve on.

I OWN MY OWN BUSINESS FOR 28 YRS

Please provide a brief statement describing your interest in serving the City of Biddeford.

TO HELP ENCOURAGE PEOPLE

Attach any additional information to this application and return it to the City Clerk's Office.

IN BOARD OF CITY COUNCIL…JANUARY 2, 2018

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Julian Schlaver
34 Union Street
Ward 5

to the *Downtown Development Commission,* for a term to expire in December 2020.

CITY OF BIDDEFORD

Application for
City Committees, Commissions and Boards

Date: 12/15/17

Name: Julian Schlaver

Street Address: 34 Union Street
BIDDEFORD MAINE 04005

Mailing Address:
(if different)

Phone Number(s): 917.301.2160

Email Address: julian@[redacted]angelrox.com jschlaver@biddefordmaine.org

---

Which City Committee, Board or Commission do you request to be appointed to:

- ____ • Airport Commission
- ____ • Biddeford Fire Advisory Committee
- ____ • Biddeford Housing Authority
- ____ • Biddeford Police Advisory Committee
- ____ • Board of Assessment Review
- ____ • Cable T.V. Committee
- ____ • Capital Projects Committee
- ____ • Conservation Commission
- ✓ • Downtown Development Commission
- ____ • Economic Improvement Commission
- ____ • Harbor Commission
- ____ • Historic Preservation Commission
- ____ • Planning Board
- ____ • Policy Committee
- ____ • Project Canopy Committee
- ____ • Recreation Commission
- ____ • Shellfish Conservation Committee
- ____ • Solid Waste Management Commission
- • Wastewater Management Commission
- ____ • Zoning Board of Appeals

CITY OF BIDDEFORD
Committee Application

Please list any prior experience serving on any Public Boards, Commissions or Committees (and approximate dates)

Downtown Development Commission 2015 - present
Mayors ad hoc Downtown Committee 2016 - 2017
Strategic planning Committee 2016

Please list any other experience that may be pertinent to the Board or Committee in which you are requesting to serve on.

I am a business Owner in the downtown with 20 employees and 3 locations (Angelrae + Sugar in Biddeford + portland) my wife and I have been active in the community and we love Biddeford.

Please provide a brief statement describing your interest in serving the City of Biddeford.

I believe in this town and its future. My son is in the public schools and we live within walking distance of the downtown. As I look at this community I feel pride and belonging and my mind races envisioning a bright and beautiful future for those who live here and visit

Attach any additional information to this application and return it to the City Clerk's Office.

IN BOARD OF CITY COUNCIL…JANUARY 2, 2018

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby re-appoint:

Nathan Bean
39 Union Street
Ward 5

to the *Policy Committee,* for a term to expire in December 2019.

CITY OF BIDDEFORD

Application for
City Committees, Commissions and Boards

Date: 12/15/17

Name: NATHAN BOND

Street Address: 39 UNION STREET
BIDDEFORD

Mailing Address:
(if different)

Phone Number(s): (207) [redacted] 571-9557

Email Address: [redacted] beau.nate@gmail.com

Which City Committee, Board or Commission do you request to be appointed to:

- ____ Airport Commission
- ____ Biddeford Fire Advisory Committee
- ____ Biddeford Housing Authority
- ____ Biddeford Police Advisory Committee
- ____ Board of Assessment Review
- ____ Cable T.V. Committee
- ____ Capital Projects Committee
- ____ Conservation Commission
- ____ Downtown Development Commission
- ____ Economic Improvement Commission
- ____ Harbor Commission
- ____ Historic Preservation Commission
- ____ Planning Board
- ✓ Policy Committee
- ____ Project Canopy Committee
- ____ Recreation Commission
- ____ Shellfish Conservation Committee
- ____ Solid Waste Management Commission
- ____ Wastewater Management Commission
- ____ Zoning Board of Appeals

CITY OF BIDDEFORD
Committee Application

Please list any prior experience serving on any Public Boards, Commissions or Committees (and approximate dates)

2015-2017 POLICY COMMITTEE

Please list any other experience that may be pertinent to the Board or Committee in which you are requesting to serve on.

CANDIDATE FOR MASTER'S IN EDUCATIONAL LEADERSHIP

Please provide a brief statement describing your interest in serving the City of Biddeford.

I AM INTERESTED IN CONTINUING TO SERVE ON THE POLICY COMMITTEE. I HAVE ENJOYED BEING INVOLVED IN CITY GOVERNMENT AND AM VERY HAPPY WITH THE CURRENT DIRECTION OF THE CITY. I WOULD LIKE TO DO MY PART TO KEEP THE CITY ON THIS POSITIVE PATH.

Attach any additional information to this application and return it to the City Clerk's Office.

City of Biddeford

IN BOARD OF CITY COUNCIL…JANUARY 2, 2018

ORDERED, that I, Alan M. Casavant, Mayor of the City of Biddeford, do hereby appoint:

Alan Dutremble
Joseph McKenney
Dominic Deschambault
Victoria Foley

to the *Ad Hoc Community Center Committee.*