TENTATIVE AGENDA & MEETING NOTICE
BOARD OF COUNTY COMMISSIONERS

TUESDAY, MARCH 20, 2018
5:30 P.M.

WATAUGA COUNTY ADMINISTRATION BUILDING
COMMISSIONERS' BOARD ROOM

TIME	#	TOPIC	PRESENTER	PAGE
5:30	1	CALL REGULAR MEETING TO ORDER		
	2	APPROVAL OF MINUTES: February 19 & 21, 2018, Special Meeting - 2018 Retreat March 6, 2018, Regular Meeting March 6, 2018, Closed Session		1
	3	APPROVAL OF THE MARCH 20, 2018, AGENDA		11
5:35	4	WATAUGA COUNTY SCHOOL SYSTEM LOTTERY FUNDS REQUEST	DR. SCOTT ELLIOTT	13
5:40	5	OPIOID LITIGATION PRESENTATION	MR. GARRY B. WHITAKER	17
5:45	6	PARKS AND RECREATION MATTERS A. Vehicle Bid Award Request B. Out-of-State Travel Request	MR. STEPHEN POULOS	 127 131
5:50	7	TAX MATTERS A. Monthly Collections Report B. Refunds & Releases	MR. LARRY WARREN	 135 137
5:55	8	MISCELLANEOUS ADMINISTRATIVE MATTERS A. Boards and Commissions B. Announcements	MR. DERON GEOUQUE	 145 149
6:00	9	PUBLIC COMMENT		151
7:00	10	BREAK		151
7:05	11	CLOSED SESSION Attorney/Client Matters – G. S. 143-318.11(a)(3) Land Acquisition – G. S. 143-318.11 Personnel Matters – G. S. 143-318.11(a)(6)		151
7:25	12	POSSIBLE ACTION AFTER CLOSED SESSION		151
7:30	13	ADJOURN		

AGENDA ITEM 2:

APPROVAL OF MINUTES:

February 19 & 21, 2018, Special Meeting – 2018 Retreat
March 6, 2018, Regular Meeting
March 6, 2018, Closed Session

DRAFT

MINUTES

WATAUGA COUNTY BOARD OF COMMISSIONERS
SPECIAL MEETING
MONDAY, FEBRUARY 19, 2018 & WEDNESDAY, FEBRUARY 21, 2018

The Watauga County Board of Commissioners held a special meeting on Monday, February 19, 2018, and Wednesday, February 21, 2018, in order to conduct a retreat to review goals and objectives for the County. The meetings were held in the Commissioners' Board Room located in the Watauga County Administration Building, Boone, North Carolina.

PRESENT: John Welch, Chairman
Billy Kennedy, Vice-Chairman
Jimmy Hodges, Commissioner
Larry Turnbow, Commissioner
Perry Yates, Commissioner
Deron Geouque, County Manager
Margaret Pierce, Finance Director

Lunch was provided at 12:00 PM. Chairman Welch called the meeting to order on Monday, February 19, 2018 at 12:40 PM, welcoming those in attendance.

The following topics were discussed:

Opening Remarks
Mr. Deron Geouque

Community Recreation Center Update
Mr. Chad Roberson & Mr. George Deines

Break from 2:05 PM to 2:25 PM

FY 2018 Review and Discussion of 2019 Budget
Ms. Margaret Pierce

1. Revenues
2. Debt Service Report
3. Budget Calendar

Review of Current Capital Improvement Plan (CIP)
Mr. Deron Geouque & Mr. Robert Marsh

1. Current CIP Status Report
    a. Relocation of County Personnel
        Planning and Inspections
        Veteran's Services
        Red Cross
    b. Courtroom #2 Renovations
    c. East Annex Building Program

d. New River Baseball Facilities
e. School Facilities
f. Update on Recreational Projects
g. Guy Ford Paddle Access

Middle Fork Greenway

Ms. Wendy Patoprsty & Mr. Joe Furman

Break from 4:15 PM to 4:35 PM

Caldwell Community College & Technical Institute

Dr. Mark Poarch

School Board Funding Issues

Superintendent Dr. Scott Elliott, School Board Members Ron Henries, Jason Cornett, Dr. Jay Fenwick, Dr. Gary Childers, and Staff members Ly Marze, Dr. Stephen Martin, Danny Clark and Consultant Chad Roberson

1. FY 2019 Funding Needs
2. Schools' Capital Improvement Plan

Children's Council Presentation

Ms. Hunter Varipapa

County Manager's Summary

Mr. Deron Geouque

A recess was declared at 6:50 PM. The meeting reconvened on Wednesday, February 21, 2018, at 9:00 AM.

Tourism Development Authority (TDA)

Mr. Matt Vincent and Mr. Wright Tilley

Watauga Housing Trust

Mr. Deron Geouque and Mr. Joe Furman

Watauga Humane Society Facilities

Mr. Charles Duke and Mr. Steve Duprey

Break 10:35 AM to 10:42 AM

Broadband Connection Efforts

Mr. Keith Conover and Mr. Joe Furman

Public Safety and Emergency Communications Systems Study Update

Mr. Marvin Hoffman and Mr. Jeff Virginia

Miscellaneous & Commissioner Matters

Mr. Deron Geouque

State Issues

Commissioners Matters

Budget work sessions set for May 2, 2018 from 12-7 PM and May 3, 2018 from 12-7 PM

Board Discussion and Directives

The County Manager concluded the retreat by reviewing the issues addressed and seeking direction from the Board for Fiscal Year 2018-2019.

The meeting adjourned at 12:25 PM

John Welch
Chairman, Watauga County Board of Commissioners

ATTEST:
Deron Geouque
County Manager

DRAFT

MINUTES

WATAUGA COUNTY BOARD OF COMMISSIONERS
TUESDAY, MARCH 6, 2018

The Watauga County Board of Commissioners held a regular meeting, as scheduled, on Tuesday, March 6, 2018, at 8:30 A.M. in the Commissioners' Board Room of the Watauga County Administration Building, Boone, North Carolina.

PRESENT: John Welch, Chairman
Billy Kennedy, Vice-Chairman
Jimmy Hodges, Commissioner
Larry Turnbow, Commissioner
Perry Yates, Commissioner
Andrea Capua, County Attorney
Deron Geouque, County Manager
Anita J. Fogle, Clerk to the Board

Chairman Welch called the meeting to order at 8:32 A.M.

Commissioner Hodges opened with a prayer and Commissioner Turnbow led the Pledge of Allegiance.

APPROVAL OF MINUTES

Chairman Welch called for additions and/or corrections to the February 20, 2018, special meeting, regular meeting and closed session minutes.

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to approve the February 20, 2018, special meeting minutes as presented.

VOTE: Aye-5
Nay-0

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to approve the February 20, 2018, regular meeting minutes as presented.

VOTE: Aye-5
Nay-0

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to approve the February 20, 2018, closed session minutes as presented.

VOTE: Aye-5
Nay-0

APPROVAL OF AGENDA

Chairman Welch called for additions and/or corrections to the March 6, 2018, agenda.

County Manager Geouque requested to add consideration of acceptance of a Tennessee Valley Authority (TVA) grant award.

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to approve the March 6, 2018, agenda as presented.

VOTE: Aye-5
Nay-0

SHERIFF'S OFFICE REQUEST TO PURCHASE NEW BODY CAMERAS AND STORAGE

County Manager Geouque requested, on behalf of Captain Kelly Redmon with the Sheriff's Office, approval of the purchase of four (4) new Axon body cameras along with licensing fees and cloud based storage. Adequate funds have been budgeted in the FY 2017-2018 budget. The current Axon plan with twelve cameras cost $12,108. The additional four cameras will cost $3,160 which brings the total to $15,268.

Commissioner Yates, seconded by Commissioner Turnbow, moved to approve the purchase of four (4) additional new Axon body cameras along with licensing fees and cloud based storage in the total amount of $15,268.

VOTE: Aye-5
Nay-0

REQUESTS FOR SOUTH FORK RESTORATION PROJECT AT THE TED MACKORELL SOCCER COMPLEX

Mr. George Santucci with the New River Conservancy presented information regarding the South Fork River restoration project adjacent to the County-owned Ted Mackorell Soccer Complex and property on the other side of the river consisting of lots owned by the Town of Boone and Hollar and Greene Produce Company. Mr. Santucci requested approval of a restricted covenant on a fifty (50) foot buffer along the County-owned property. In addition he requested that the County hold a conservation easement on the Hollar and Green property. These restrictions and easements are required by the Clean Water Management Trust Fund (CWMTF) to ensure funding for the project.

Commissioner Turnbow, seconded by Vice-Chairman Kennedy, moved to grant a fifty (50) foot restricted covenant buffer on the County-owned property located at the Ted Mackorell Soccer Complex and to hold the conservation easement for the Hollar and Greene Produce Company property related to this project.

VOTE: Aye-5
Nay-0

Discussion was held to clarify if Hollar and Greene had approved the conservation easement. Mr. Santucci said that they were in agreement. Mr. Joe Furman stated that Hollar and Greene Produce would have to allow the County an easement to their property on which the restricted covenant could be placed.

After discussion, Commissioner Yates, seconded by Commissioner Turnbow, moved to accept an easement from Hollar and Greene in order to place the restricted covenant as approved in the prior motion.

VOTE: Aye-5
Nay-0

PROPOSED PRE-APPLICATION FOR AN APPALACHIAN REGIONAL COMMISSION (ARC) GRANT FOR SECTION 4 OF THE MIDDLE FORK GREENWAY

Mr. Joe Furman, Planning and Inspections Director, requested permission to submit a pre-application for $300,000 to the Appalachian Regional Commission (ARC) for funds for the Middle Fork Greenway, Section 4. The ARC rates counties by "level of distress" and determines the required grant match accordingly. Watauga County is considered an "at risk" County; therefore, the maximum percentage of the cost of the project ARC funds can cover is 70%. The estimated cost of the project is $1.8 million; the $300,000 (which is the maximum amount that can be requested) will not approach the 70% that would be covered by ARC funds.

Mr. Furman stated that the Blue Ridge Conservancy (BRC) is also an eligible applicant and they are in the process of determining which entity has a better chance of being funded. If the determination is made that BRC should be the applicant, the County would not apply.

Mr. Furman stated that, if the County applies, he would know by early summer if the ARC planned to invite the County to submit a full application.

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to approve the submission of the grant pre-application contingent upon it being determined that the County would be the more suitable applicant.

VOTE: Aye-5
Nay-0

REQUEST TO ACCEPT TENNESSEE VALLEY AUTHORITY GRANT FUNDS

Mr. Joe Furman stated that the Tennessee Valley Authority (TVA) has granted Watauga County an amount not to exceed $50,000 for work on the Guy Ford Road River Access project. Mr. Furman presented the proposed Cooperative Agreement from the TVA and requested the Board accept the grant award from the TVA.

Commissioner Yates, seconded by Commissioner Hodges, moved to accept the Tennessee Valley Authority grant award in an amount not to exceed $50,000 as presented by Mr. Furman.

VOTE: Aye-5
Nay-0

BOARD OF EQUALIZATION AND REVIEW SCHEDULE

Mr. Larry Warren, Tax Administrator, discussed the scheduling of the FY 2018 Board of Equalization and Review (E&R). Mr. Warren recommended the convening date for the Board of Equalization and Review be scheduled for Wednesday April 18, 2018, at 2:30 P.M. and the adjournment of the Board be scheduled for Thursday April 26, 2018, at 5:00 P.M. The Board discussed other meeting dates as well.

Commissioner Yates, seconded by Commissioner Turnbow, moved to set the following dates for the Board of Equalization and Review:

- Convene on Wednesday, April 18, 2018, at 2:30 P.M.
- Meet on Thursday, April 19, 2018, from 4:00 – 7:00 P.M.
- Meet on Monday, April 23, 2018, from 4:00 – 7:00 P.M.
- Meet on Thursday, April 26, 3018, from 4:00 – 7:00 P.M.
- Adjourn on Thursday, April 26, 2018, from 4:00 – 5:00 P.M.

VOTE: Aye-5
Nay-0

Mr. Warren stated that the Board may create a special Board of Equalization and Review or, as in previous years, the Board of Commissioners may serve as the Board of Equalization and Review and include the County Manager to serve as an alternate member. The County Manager would only serve if a quorum could not be met otherwise. A proposed resolution establishing the Board of Equalization and Review was presented. Mr. Warren stated that the Board of Equalization and Review has been compensated $75 per meeting in the past. County Manager Geouque clarified that he would not receive compensation.

Vice-Chairman Kennedy, seconded by Commissioner Turnbow, moved to adopt the resolution and establish the compensation rate for the Board of Equalization and Review at $75.00 per meeting.

VOTE: Aye-5
Nay-0

MISCELLANEOUS ADMINISTRATIVE MATTERS

A. Proposed Lease Renewal - Daymark Recovery

County Manager Geouque presented a proposed lease renewal with Daymark Recovery Services, Inc. The County Manager stated that the current lease is set to expire June 30, 2018. The County Attorney has reviewed and updated the existing lease to allow for another three (3) year

term. The conditions are proposed to remain the same. If approved, the lease will be forwarded to Daymark Recovery Services for their approval.

Commissioner Yates, seconded by Commissioner Turnbow, moved to approve the lease with Daymark Recovery Services effective July 1, 2018, through June 30, 2021, and as set forth in the lease.

VOTE: Aye-5
Nay-0

B. Boards and Commissions

County Manager Geouque presented the following for consideration:

WAMY Community Action
Ms. Joy Coffey's final term as a Public Sector representative for Watauga County expired on February 8, 2018. Ms. Melissa Soto, Executive Director of WAMY, requests a Commissioner or appointee be appointed to fill the four-year term. There is one position to fill. Mr. George Winkler has expressed some interest to Ms. Soto.

Ms. Soto has stated that the WAMY Board meets bi-monthly on the 2nd Tuesday at 5:00 P.M. The meetings are held in the Commissioners' Board Room in Avery County. The next meeting is their Board Retreat (and a great time for a new member to begin) which will be held in the Boone office on April 7 at 10:00 A.M. The next regular meeting will be May 8.

Consideration was tabled to allow for Mr. Winkler to submit a volunteer application if he is interested in serving.

High Country Workforce Development Board
Mr. Keith Deveraux, Director of the High Country Workforce Development Board (WDB), has recommended the appointment of Mr. Hayden Gibson to serve on the WDB.

Commissioner Yates, seconded by Commissioner Turnbow, moved to waive the second reading and appoint Mr. Hayden Gibson to the High Country Workforce Development Board.

VOTE: Aye-5
Nay-0

Blowing Rock ETJ Representative for Planning Board and Board of Adjustment
Mr. Kevin Rothrock, Blowing Rock Planning Director, stated that the Blowing Rock Town Council recommended Mr. Harrison Herbst to serve as an Extra-territorial Jurisdiction (ETJ) representative on both the Blowing Rock Planning Board and Board of Adjustment.

Commissioner Yates, seconded by Commissioner Turnbow, moved to waive the second reading and appoint Mr. Harrison Herbst to serve as an Extra-territorial Jurisdiction representative on the Blowing Rock Planning Board and Blowing Rock Board of Adjustment.

VOTE: Aye-5
Nay-0

C. Announcements

County Manager Geouque announced the following:

- Watauga County Cooperative Extension invites you to the Annual "Report to the People" on Tuesday, March 13, from 11:45 A.M. to 1:00 P.M. at the Agricultural Conference Center. The staff plans to prepare a homemade lunch, and Extension Director, Jim Hamilton, will briefly present an update.

PUBLIC COMMENT

There was no public comment.

CLOSED SESSION

At 9:03 A.M., Commissioner Hodges, seconded by Commissioner Turnbow, moved to enter Closed Session to discuss Attorney/Client Matters, per G. S. 143-318.11(a)(3) and Personnel Matters, per G. S. 143-318.11(a)(6).

VOTE: Aye-5
Nay-0

Vice-Chairman Kennedy, seconded by Commissioner Yates, moved to resume the open meeting at 9:37 A.M.

VOTE: Aye-5
Nay-0

POSSIBLE ACTION AFTER CLOSED SESSION

There was no action after Closed Session.

ADJOURN

Commissioner Turnbow, seconded by Vice-Chairman Kennedy, moved to adjourn the meeting at 9:37 A.M.

John Welch, Chairman

ATTEST:
Anita J. Fogle, Clerk to the Board

AGENDA ITEM 3:

APPROVAL OF THE MARCH 20, 2018, AGENDA

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AGENDA ITEM 4:

WATAUGA COUNTY SCHOOL SYSTEM LOTTERY FUNDS REQUEST

MANAGER'S COMMENTS:

Dr. Scott Elliott, Watauga County Schools Superintendent, will provide an update on school matters and request funds from the Education Lottery Funds. A total amount of $117,500 is being requested. $60,000 is to replace the phone intercom and bell systems at Cove Creek Elementary School and $57,500 for a new fire alarm system at Valle Crucis Elementary School.

Board action is required to approve the $117,500 request for lottery funds to be utilized for phone intercom, bell, and fire systems.

APPLICATION
PUBLIC SCHOOL BUILDING CAPITAL FUND
NORTH CAROLINA EDUCATION LOTTERY

Approved: _____

Date: _____

County: Watauga County
LEA: Watauga County Schools
Address: 175 Pioneer Trail, Boone, NC 28607

Contact Person: Ly Marze
Title: Finance Officer
Phone: 828-264-7190

Project Title: Replace phone intercom and bell systems
Location: Cove Creek School, 930 Vanderpool Rd, Vilas, NC 28692
Type of Facility: K-8 School

North Carolina General Statutes, Chapter 18C, provides that a portion of the proceeds of the North Carolina State Lottery Fund be transferred to the Public School Building Capital Fund in accordance with G.S. 115C-546.2. Further, G.S. 115C-546.2 (d) has been amended to include the following:
(3) No county shall have to provide matching funds…
(4) A county may use monies in this Fund to pay for school construction projects in local school administrative units and to retire indebtedness incurred for school construction projects.
(5) A county may not use monies in this Fund to pay for school technology needs.

As used in this section, "Public School Buildings" shall include only facilities for individual schools that are used for instructional and related purposes, and does not include central administration, maintenance, or other facilities. ***Applications must be submitted within one year following the date of final payment to the Contractor or Vendor.***

Short description of Construction Project: Replace school building phone, intercom, and bell systems

Estimated Costs:

Purchase of Land	$	
Planning and Design Services		
New Construction		
Additions / Renovations		60,000.00
Repair		
Debt Payment / Bond Payment		
TOTAL	$	60,000.00

Estimated Project Beginning Date: March 2018
Est. Project Completion Date: August 2018

We, the undersigned, agree to submit a statement of state monies expended for this project within 60 days following completion of the project.

The County Commissioners and the Board of Education do hereby jointly request approval of the above project, and request release of $ 60,000.00 from the Public School Building Capital Fund (Lottery Distribution). We certify that the project herein described is within the parameters of G.S. 115C-546.

_____
(Signature — Chair, County Commissioners) (Date)

_____
(Signature — Chair, Board of Education) (Date)

Form Date: July 01, 2011

APPLICATION
PUBLIC SCHOOL BUILDING CAPITAL FUND
NORTH CAROLINA EDUCATION LOTTERY

Approved: _____

Date: _____

County: Watauga County
LEA: Watauga County Schools
Address: 175 Pioneer Trail, Boone, NC 28607

Contact Person: Ly Marze
Title: Finance Officer
Phone: 828-264-7190

Project Title: Fire Alarm Replacement
Location: Valle Crucis School, 2998 Broadstone Rd, Sugar Grove, NC 28679
Type of Facility: K-8 School

North Carolina General Statutes, Chapter 18C, provides that a portion of the proceeds of the North Carolina State Lottery Fund be transferred to the Public School Building Capital Fund in accordance with G.S. 115C-546.2. Further, G.S. 115C-546.2 (d) has been amended to include the following:
(3) No county shall have to provide matching funds…
(4) A county may use monies in this Fund to pay for school construction projects in local school administrative units and to retire indebtedness incurred for school construction projects.
(5) A county may not use monies in this Fund to pay for school technology needs.

As used in this section, "Public School Buildings" shall include only facilities for individual schools that are used for instructional and related purposes, and does not include central administration, maintenance, or other facilities. ***Applications must be submitted within one year following the date of final payment to the Contractor or Vendor.***

Short description of Construction Project: Replace non-working fire alarm in school

Estimated Costs:

Purchase of Land	$	
Planning and Design Services		
New Construction		
Additions / Renovations		57,500.00
Repair		
Debt Payment / Bond Payment		
TOTAL	$	57,500.00

Estimated Project Beginning Date: March 2018
Est. Project Completion Date: August 2018

We, the undersigned, agree to submit a statement of state monies expended for this project within 60 days following completion of the project.

The County Commissioners and the Board of Education do hereby jointly request approval of the above project, and request release of $ 57,500.00 from the Public School Building Capital Fund (Lottery Distribution). We certify that the project herein described is within the parameters of G.S. 115C-546.

_____
(Signature — Chair, County Commissioners) (Date)

_____
(Signature — Chair, Board of Education) (Date)

Form Date: July 01, 2011

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AGENDA ITEM 5:

OPIOID LITIGATION PRESENTATION

MANAGER'S COMMENTS:

Attorney Garry B. Whitaker will discuss with the Board the current opioid lawsuit. An overview will be provided and Mr. Whitaker will inquire if Watauga County would like to join the lawsuit and the necessary actions required to be taken if the Board so chooses to participate. The Board may wish to consult with the County Attorney in closed session before official action is taken.

Staff seeks direction from the Board.

Forum on Opioid-Related Legal Matters
November 15, 2017

Amy intro remarks

Fuller
Working with a lot of local counsel
Buncombe case filed yesterday

Farrell
WV AG sued everyone when he filed
Shift in how cases are being prosecuted; Cardinal Health lobbyist
Eric Eyre, FOIA request
Nov 2016 headlines revealed in 6 year window, huge number of opioids prescribed
Father is chief judge and huge problem with abuse and neglect
AG settled cases, Fuller decided to do something about it
Studied WV law, legislature gives county commission authority to eliminate hazards to public safety and nuisance
Public nuisance law; mostly lead paint and handgun cases
Transactions were lawful at the time, framework he was working with
What was AG trying to settle and how does it apply to him
Controlled Substances Act of 1970
Closes the system of distribution
Controlled substances are so dangerous, we're going to close the system and create a chain of distribution, comes with rules for quality control
Sales couldn't be direct, economic incentive for more sales so created a middle man – wholesale distributor; 3 companies distribute 80% of opioids; McKesson biggest
Distributor responsible for ID, halt and report suspicious orders; orders of unusual size, frequency and deviation of normal pattern
Every transaction has to be recorded in ARCOS database
But need more resources
Office of Diversion Control created in 2006
Ranisidy letters (in their packet)
2008 Ranisidy did first audit in FL at Cardinal Health facility; selling same amount of opioids to five pharmacies as rest of their entire distribution
DEA revoked them after continued abuse
$40 million fine to Cardinal
$150 million fine to McKesson
Didn't change either's stock prize
Economic incentive for speeding is worth it to them
Describes how addiction progresses with addition of drugs, etc.
2011, Obama said community problems require community solutions
Describes how community money is diverted to services that address the opioid issue vs. other maintenance issues – bridges, boilers, etc.

Focusing on education of elementary school students
Issue that germinates – have to contain the outbreak by inoculating children
Proposing $5M in first 10 years for nothing but education in his hometown
Have to keep people safe, focusing on law enforcement
Have to turn attention to lost generation, grandparents raising grandchildren
Gathering key stakeholders to discuss what is needed
Thinking big about tackling the problem
1500 violations of federal law – he wants to stand before a WV jury and present this
Unlawful conduct over a decade
Damage model that not only includes money spent on this but also the money that would have been required to handle the other items that didn't get addressed as a result
Manufacturers sitting on data that was essentially a kick back to them
Book called Dreamland, his hometown as focus
Reached out to people in his network to gather
In 10 states
Cases get centralized in each state
Filed petition to have it moved to MDL
Nov 30 in St. Louis hearing
OH, Judge Edwin Sargus
As soon as MDL panel rules, will be in OH, WV or XX?
Distributors have told DEA that they think the DEA is wrong and that it wasn't their job to monitor and report
Decision was appealed Masters vs. Pharma; industry lost
Affirmed in DC court of appeals
Feel they have a strong liability case
What about the AG – they're getting involved, some claim they have authority to file on behalf of state, state has its costs, communities also have their costs
Think counties can come together and be transformative
They're focused on distributors, other firm focused on manufacturers
Train tracks have merged
Sees this as a volume problem
Spoke about China and the historical problem of opioid use; tried to abolish East India Company
Early 1900 record of Mr. McKesson bringing sunlight to issue
NC has obnoxious opioid sales, have a problem
Heroin(e) documentary story of three women trying to address the issue

Question about physician prescribing habits, pharmacists

- Definitely a problem, have to bring accountability; know who they are and where; now hidden behind ARCOS database, will be pursue
- Licenses need to be revoked

Have they tried to third party in the physicians and pharmacists

- Pharmacists – we're not doctors
- Cardinal Health brought doctors and pharmacists to conversation

- Could happen, but will bring sunlight to issue
- Probably won't do it because will bring RICO claims
- Under RICO, federal peer joint civil liability, doesn't do them any good, drives up damages model

Dreamland

- Black tar, how plant can be used and processed
- Pills are isolation of poppy plant
- Black tar heroin is same beast in different packaging

Local pharmacies

- Have contracts with distributors, will impact their business, how do we approach these people who are leaders in our communities
- Will change business model, need to figure out another way to make money
- Economic shift will happen because of reduction in manufacturing quota
- What we can tell pharmacists to do – go to State board of pharmacy – tell them to start doing their job
- Fuller has reached out to pharmacy and physician associations to discuss, but they're cautious
- Haven't brought suit against doctors or pharmacies, focused on volume – manufacturers and distributors
- Congress made a channel to prescribe these medications, but they were flooded in the community and need to return back to channel (analogy to river banks)

Dickinson
Represent dozens of counties in these lawsuits
Will focus on the litigation – how and with who
Counties have born the cost of the epidemic
Was approached to look at cases in her state, Wisconsin
Will be the only firm rep'ing counties in WN
Did research to determine which firms know the most about issue to see who she wants to work with
Believes Paul Hanly to be the most knowledgeable about opioid litigation
Have been on a journey for about eight months to pursue this issue

Hanly
Only represent plaintiffs on contingency fee basis
80 lawyers, 240 support staff in six cities; HQ in IL
Hanly first filed OxyContin lawsuits in 2003, against Purdue Pharma and Abbot Laboratories; focused on drug companies' fraudulent marketing campaign
Asbestos case proceeds help fund their other cases
Essentially invented opioid litigation
5000 individuals rep'd in litigation, settled in 2007 for substantial sum
Heard from medical professionals that they saw increase in patient addiction, lawful prescribing
Purdue Pharma invented OxyContin, pointed to them in particular
Thousands of patients didn't set out to become addicted but ultimately did
Pursued clients who were lawfully prescribed and followed doctor's orders, acquired 5000 clients

Learned manufacturer created edifice of false science, told doctors the drugs were not addictive
Time release feature of OxyContin (Contin = continuous) would mean that there wouldn't be spikes of narcotic so patient wouldn't become addicted
It was made up, no science to support it; emanated from marketing dept at Purdue
Not a class action, filed individual lawsuits against Purdue
Purdue was forced to release internal documents to show how OxyContin was developed; fraud
US DOJ wanted to make criminal case against Purdue, came to Hanly to get evidence they gathered
US prosecuted on basis of criminal mis-branding; pleaded guilty $600M fine; three execs paid $10-20M each
Purdue settled 5000 cases, Hanly can't tell about it but reported to be settlement of $75M
Developed robust knowledge of manufacturing, distribution and sale of opioids
In the decade since, have been called on by various govt agencies to share knowledge
Nothing really happened until 2015 litigation
Contacted by Suffolk County, NY to discuss investigating liability of claims by county and determine viability
Theories of liability in Oxy I – negligent promotion, consumer fraud, failure to warn; concluded good claims; filed first Suffolk lawsuit in 2016
Have been contact many times since, now rep'ing about 100 counties and cities in county
Goal to rep as many 1000 counties in next year
Discovery uncovered that defendants knew that opioids were not safe or efficacious for long term use, defendants created well funded campaign to deceive med community and patients that these drugs were safe and efficacious for long term use; their goal was to flip generally accepted science on its head and they were successful
For 100 years, med community accepted idea/general wisdom that painkillers have very limited use – amputation, major fractures, end of life
Companies convinced that the drugs weren't addictive; used advertising, etc., to peddle this nonsense
Manufacturers started this issue, others guilty but manufacturers started this
Other manf adopted same lies as Purdue
Purdue mantra was that addiction was very rare; relied on studies that had nothing to do with OxyContin, in-patient pain management, not home use
Omitted contrary addiction studies and data
Relied on studies that addressed the use of opioids after trying more traditional methods
Used unbranded and unregulated marketing materials to create a phony "scientific consensus" – put them in doctors offices
Use front groups and key opinion leaders (doctors who they paid millions) to create a false medical consensus
Letter to Editor in "The Porter & Jick Letter" – cited 700 times by drug manufacturer to indicate "Addiction Rare in Patients Treated with Narcotics" – N. Engl J Med 1980: 123-123; based on instances of word "addiction" in medical chart
Dr. Jick testified he was appalled that anyone would take letter to use it in support of claiming not addictive
J&J opioid myths summary – completely false (American Academy of Pain Medicine – one of the front groups)
Interconnections graphic that shows the lines between players in industry

55 cases on file currently, have to file about 40+ more
Currently only suing manufacturers, think bang for the buck is in the claims against manf
Keeping an open mind to distributor claims but feel the case against the manf is so clear; think the claim against the distributors less clear
Claims to consider slide

Dickinson
Litigation will be split into two types of cases – state and federal
Most counties, unless there is a local manf, will find themselves in federal court
Their view is that unless there is a good diverse defendant in state jurisdiction, then in all likelihood will be in federal court
Will likely be consolidated in MDL, will proceed on a national basis for much of the litigation together
Means there will national team running the cases across the counties; will have direction and control over important aspects of pre-trial litigation; will have influence over the terms of any settlement that is reached
Need to get a firm that has national focus, coordinated team
Timing is important as motion to consolidate cases in MDL has been filed; Nov 30 hearing in St. Louis
Counties can petition to have their attorneys appointed to lead that litigation in early 2018
Try to decide what to do before end of year
By ~ March 2018, leadership committee will likely be set – this is the point where to get the best advantage to have your lawyers hired so you have representation on leadership committee
Otherwise lawyers may not have a seat at table to be a part of decision making process, have a voice
Big pharma will be organized and coordinated in its defense of this litigation
Can bring suit later, not statute of limitations issue; just a consideration to get best consideration
Many defendants and theories; panel may split manf and distributor claims
Unprecedented in number of defendants being pursued
More unified plaintiffs can be, the better; big pharma will definitely by coordinated; filing same day impactful
Provided a sample resolution and engagement letter
Consider whether we can organize a list of counties who can bring the cases together
Coordinating within state and nationally; uniformity of approach and facts
Can schedule follow-up call

Wood/AG
Update on where they are in civil investigation
Kevin Anderson, years of experience in MDL; leading team of 12 actively involved in this investigation
AG Stein came into office dealing with opioid crisis as number one priority, nothing more important in their department
Was a motivation for running for the office
Three-part strategy: 1) prevention (change prescribing practices – STOP Act signed into law June 29, 2017, change behavior or drug companies), 2) treatment, 3) enforcement – civil and criminal
Next focus is civil investigation and role litigation can play in addressing it – tied to reality or threat of civil litigation can be motivator for drug companies to change behavior

Bipartisan multi-state investigation – NC in lead group on executive committee, 41 AG offices; Kevin Anderson leading the effort for NC
Parallel tracks – active investigation building evidence, active engagement with drug companies to explore resolution; against all available targets – people, companies – for their role in this crisis
Pursuing both vigorously, one not getting more attention than the other
As the state, we hold ourselves to a higher standard than other plaintiffs; want to make sure they have all ducks in a row so that it's a clear case
State sometimes can have access to investigative tools that other plaintiffs wouldn't until filing
Key objectives: meaningful remedies that match the scale and reach of the problem - monetary relief and behavior changes; accountability; time – overwhelming need exists now
Current status – investigative track ongoing for month, have gathered huge number of documents building toward filing civil actions
Counties and cities at the forefront of everyone's thinking – states and defendants
Discussions with drug companies are at a delicate stage; legit concern that if there is a flood of county lawsuits filed, it will materially hurt the current state of the settlement
Discussions will either go somewhere or not, clock not unlimited

Question (from Fuller) about whether it's intention to settle on behalf of counties and cities

- Opt in process could be the process
- Goal to obtain meaningful relief that would reach all areas that have been affected including counties; premature to say specifically

Question about whether seeking to participate in MDL or handle your litigation separately

- If/when deciding to file lawsuit, will do in most opportune venue
- Like to be in state court, often don't like to be in federal court
- State has litigated in federal court

Question about element of damages that locals would seek to recover

- Can't say there's nothing, but large amount of potential overlap
- Could local govts join in with state – there's a chance, haven't researched closely himself

Who would appropriate funds they recover

- Statutes control some aspects of appropriations
- Some exceptions, restitution

Access to state level data – DHHS, in discussions with DEA to get access to ARCOS data, Medicaid investigations people have access

Will you make data available to counties – depends on what restrictions are placed on AG office

Any current plan to provide data to Buncombe County – haven't been asked, want to stay in touch, want to help

Offer from Fuller about including AG's office in protective order if they get access to ARCOS data through OH request, mid-December

How can this be handled differently than what we saw with tobacco settlement – keep us informed, aware of county's view of how that settlement was handled

Question about assuming 50 counties file and 50 don't, who benefits if state recovers money – would hope we could take care of everyone but could be legal issues that preclude that, not sure how that would play out; can do it based on various metrics but need appropriate metric, want to bring that same level of granularity, rough justice, won't be down to penny

Is your office in consultation with medical society, pharmaceutical association – in coordination with all players

Can you agree that the counties have different damages than state as whole – direct loss to state is different than direct loss to counties; is there enough money to go around; key objective is to ensure the way the money goes around is in direct relation to who's been impacted

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North Carolina Opioid Litigation Memorandum

Privileged and Confidential

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Overview Memorandum

CLAIMS AGAINST OPIOID DISTRIBUTORS AND MANUFACTURERS

The country is in the midst of a public health crisis stemming from the flood of opioids pouring into her cities and counties. The opioid epidemic has been fueled by the greed of the corporate elite, such as Fortune 500 behemoth McKesson Corp., failing to detect and report "suspicious" orders of opioids, despite being required to do so by federal and state law. ***In January 2017, McKesson, the largest drug distributor in the nation, was fined a record $150 million by the federal government for its blatant failure to report suspicious orders in violation of federal law. Cardinal Health, another member of the "Big Three" drug distributors, was fined $44 million for its own failures to report suspicious narcotic orders to the DEA.***

Substantially all prescribed opioids *must* flow through the distributors: federal law requires that opioids be distributed through a closed system. The role of the distributors in this chain is to spot and report red flags in the distribution chain.

McKesson, Cardinal and their distributor cronies admit that they are the gatekeepers – the watch dogs – for preventing opioid abuse, stating: "***distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances. . . and reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.***"[1] The distributors make this admission in the Industry Compliance Guidelines they themselves created to comply with legal mandates – and then wholly ignored.

Instead of instituting controls to stop opioid abuse and alerting authorities to suspicious orders, the distributors instead have chosen to abuse their privileged position, lining their pockets by shipping massive quantities of drugs to pharmacies and dispensaries without performing any checks. The cities and counties impacted by effects of this corporate greed are left to pay the freight for this malfeasance through increased healthcare and law enforcement costs - and through the lives of their citizens.

The duty to report to the DEA suspicious orders of opioids extends to opioid manufacturers as well. ***One opioid manufacturer, Mallinckrodt, recently paid a $35 million penalty to the DEA due to its complete failure to report suspicious orders of opioids.*** Also, opioid manufacturers have a long history of mismarketing these drugs and attempting to increase the demand amongst consumers by drastically downplaying the significant risk of addiction that accompanies the use of these controlled substances. ***Significantly, Purdue Pharma has paid over $600 million to settle civil and criminal allegations related to their mismarketing of their drug OxyContin.***

Additionally, investigation into the operations of both the wholesale distributors and the manufacturers of opioids has shown that these entities have worked hand-in-hand to maximize the amount of drugs they have flooded into local communities while completely disregarding their duty maintain effective controls against diversion and halt suspicious sales of opioids. Due to the

[1] *See* Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines" or "Guidelines").

targeted and concerted action by the opioid distributors and manufacturers, these entities should be jointly and severally liable for all damages caused by their callous behavior.

Cities and counties have the means to hold these distributors and manufacturers accountable for their actions and to stop the influx of these powerful drugs. Federal and many state laws require distributors and manufacturers to identify, investigate, and report suspicious orders of controlled substances.

The distributors' and manufacturers' known violations of these laws give rise to strong claims for significant equitable and monetary relief. Distributors of opioid medications are vulnerable to damage claims and penalty actions under theories such as public nuisance, negligence, and RICO. Potentially recoverable damages may include (1) money wrongfully paid for opioids through government-payor programs including employee insurance; (2) costs for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (3) costs for providing treatment, counseling, rehabilitation services; (4) costs for providing treatment of infants born with opioid-related medical conditions; (5) costs for providing welfare or protective services for children whose parents suffer from opioid-related disability or incapacitation; and (6) costs directly associated with law enforcement and public safety relating to the opioid epidemic. Local governments may also be entitled to injunctive relief to prevent further unlawful distribution of these drugs.

This memorandum identifies causes of action through which cities and counties can hold responsible the distributors and manufacturers of opioids who have fueled the opioid epidemic.

I. Wholesale Distributors and Manufacturers Are Required under Federal Law to Monitor for and Report Suspicious Orders of Opioids.

A. The Role of Wholesale Distributors in the Opioid Distribution Chain.

Pharmaceutical distributors are supposed to play the role of "beat cops" in preventing the flow of controlled substances to abusers.

Congress enacted the Controlled Substances Act ("CSA") in 1970 with the express purpose of creating a "closed system" for the distribution of controlled substances designed to prevent the diversion of legally produced controlled substances into illicit markets.[2] Through the CSA, Congress stripped the manufacturers of the ability to sell directly to retailers, intentionally creating a link in the chain of distribution between Big Pharma and the pharmacies. This link is the wholesale distributor.

[2] *See* 21 U.S.C.A. §§ 801-971 (2006); 21 U.S.C.A. §§ 1300-1321 (2009); H.R. Rep. No. 91-1444; 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

There are only 800 registered wholesale distributors in the United States. Three Fortune 500 companies own 85% of the market share: Cardinal Health, AmerisourceBergen and McKesson Corporation. Each company generates over $100 billion in revenue annually.

Because the CSA creates a "closed system" in which opioid dispensers – like pharmacies – must obtain opioids from opioid distributors, these distributors are "uniquely situated" to spot red flags in the opioid chain, as they note in their own industry guidelines. The distributors are the first line of defense against the diversion of these drugs that can lead to abuse, addiction, and blight.

The closed chain of distribution under the CSA is designed to ensure that all controlled substances are accounted for as they make their way from the manufacturer to the end user. As would be expected, all who encounter controlled substances within the distribution chain are required to keep meticulous records. For example, pursuant to 21 C.F.R. § 1305.13(d) distributors of controlled substances must forward a copy of every order filled to the DEA.

B. Wholesale Distributors Are Required to Monitor for and Report Suspicious Orders of Opioids under Federal Law and the Law of Many States.

To further combat diversion of controlled substances, the distributors are legally required under federal law to be on alert for suspicious controlled substance orders by pharmacies – such as orders of unusual size, frequency, or pattern – and to report these unusual orders to the relevant authorities so that they can be investigated.

Federal law charges registered wholesale distributors with the non-delegable duty to "design and operate a system to disclose . . . suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

While the suspicious order reporting requirement is certainly entrenched in federal law, many states have taken the additional step of making this a state law requirement as well. States such as West Virginia, Indiana, and South Carolina, among others, require wholesale distributors to report suspicious orders of opioids to their state pharmacy boards.

C. Wholesale Distributors Have Been Warned of and Have Admitted Their Obligations.

The distributors have been on specific notice of their duties with regard to suspicious orders since at least September 2006, when the DEA sent distributors letters referencing the federal CSA monitoring and reporting requirements and providing guidance on what may constitute a "suspicious order." These letters identified diversion and abuse of controlled prescription drugs as a "serious and growing health problem," commanded that "distributors must be vigilant" in determining who can be trusted to receive controlled substances, reminded distributors of their

obligation to identify and report suspicious orders, and provided guidance on what circumstances may be indicative of diversion.

The wholesale distributors have readily admitted their monitoring and reporting obligations. The major pharmaceutical distributors (the potential defendants here) are members of the Healthcare Distribution Alliance ("HDA") (known until mid-2016 as the Healthcare Distribution Management Association, or "HDMA"), a trade association that represents pharmaceutical distributors throughout the Americas. Such members include, for example, McKesson, AmerisourceBergen and Cardinal Health, the heads of which also sit on the HDA executive committee and board. This membership is significant because, in response to DEA requirements that distributors investigate and report any suspicious controlled substance orders, HDA created "Industry Compliance Guidelines" for pharmaceutical distributors. These Guidelines, which were developed with the "strong endorsement and expertise of [HDA] members" not only function as admissions of the member distributors' duties, but also serve to set out the industry standards to which these distributors may be held.

The distributors created these Guidelines "in recognition of a growing problem of misuse and diversion of controlled substances," so that the distributors could "further scrutinize purchase orders for these products," as they were required to do by law. As noted above, the distributors admit that they "are uniquely situated to perform due diligence in order to help support the security" of controlled substance distribution.[3]

The Guidelines set out "Know Your Customer Due Diligence" standards with respect to all distributor customers – which, in the context of the Guidelines, comprise pharmacies and other legal dispensaries. These due diligence standards include gathering detailed information on the customer base of a pharmacy, the quantity of prescriptions filled each day, the quantity of controlled substance prescriptions filled each day, and the percentage of controlled substance purchases compared to overall purchases, and then utilizing this information to compare orders to a "threshold" profile to identify orders of unusual size, frequency or pattern. When confronted with "unusual" orders, the distributors' own Guidelines dictate that they should stop the shipments, investigate the orders under steps that are listed in the Guidelines, and report the suspicious activity to the DEA. These industry standards clearly establish that the duty of care for pharmaceutical distributors includes identifying, investigating, and reporting suspicious orders of controlled substances.

Distributors have chosen to abandon their duties, thereby enabling the diversion of opioids and helping to create the present epidemic. The distributors have not performed adequate due diligence and have failed to report suspicious orders, breaching the very industry standards they, themselves, created. In doing so, the distributors have violated their duties of care and both federal and state law.

D. "ARCOS" Data Contains Key Evidence of the Distributors' Breaches.

[3] *See* HDMA Industry Compliance Guidelines.

One of the ways wholesale distributors are to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders System (ARCOS) database.[4] This database contains monthly reports from each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis.

The wholesale distributors were required to monitor this data for suspicious orders. When "suspicious orders" were identified based on this regularly reported data, the wholesale distributors were required to halt shipment, perform an on-site investigation, determine whether a risk of diversion is present, and report the threat of diversion directly to the relevant authorities, including the DEA. "Suspicious orders" are defined by guidance letters provided by the DEA as well as corporate policies and industrial practices, federal law, and state law, which further define the term. For instance, any pharmacy order which exceeds 10% of the prior month's order would be considered a "suspicious order." [5]

The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. That changed when a journalist from the Charleston Gazette gained access to records sealed in a lawsuit filed by the West Virginia Attorney General against the wholesale distributors. The data revealed that 780 million prescription opiates were distributed in West Virginia (population 1.8 million) during a six-year window of time. The journalist, Eric Eyre, recently won the Pulitzer Prize for his investigative journalism.

Cities and counties have the ability through local law enforcement and cooperation with the DEA to seek and obtain historical ARCOS data. Because this information contains a record of every order filled by each pharmaceutical distributor, a review of those orders would allow for a determination of how many suspicious orders were not flagged by the distributors.

This lack of real-time monitoring and reporting by the distributors stripped cities, counties and the DEA of their ability to timely identify, investigate, and prevent the diversion of the highly addictive drugs at issue.

E. The Duty to Report Suspicious Orders Extends to Opioid Manufacturers

In July of this year, the DEA for the first time sanctioned an opioid manufacturer for failing to report suspicious opioid orders. Pursuant to a memorandum of understanding between manufacturer Mallinckrodt and the DEA, Mallinckrodt paid a $35 million civil penalty for violating federal laws that mandate suspicious order reporting.

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[4] *See United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).

[5] *See Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).

Specifically, Mallinckrodt was operating what is known in the industry as a "chargeback" system. Mallinckrodt sold opioids to a wholesale distributor at a higher than usual price, and then offered the distributor a substantial rebate in exchange for the distributor's downstream customer sales information or "chargeback data". This chargeback data allows manufacturers, like Mallinckrodt, to obtain knowledge of suspicious opioid orders. Manufacturers of controlled substances are under the same legal obligations as distributors to prevent drug diversion and are similarly required to notify DEA of suspicious orders received from their customers. The Mallinckrodt-DEA agreement requires that manufacturers review chargebacks and other data and report suspicious orders in underlying sales from distributors to downstream customers.

The "chargeback" system is not unique to Mallinckrodt. Our investigation has discovered that this practice is widespread throughout the industry, and that manufacturers have embraced shipping suspicious orders of opioids as an integral part of their business model. Therefore, manufacturers of opioids such as Purdue Pharma, Teva, Endo, Cephalon, and Janssen may also be liable for opioid-related damages.

Distributor Defendants:

The three largest pharmaceutical distributors, the "Big Three," are McKesson Corp., Cardinal Health, and AmerisourceBergen. 2016 revenues for each were approximately $147 billion, $97 billion, and $133 billion, respectively. The Big Three are all members of HDA, and their presidents and CEOs sit on the HDA Executive Committee and Board.

The Big Three have been subject to heavy fines and/or investigation for their failure to monitor for and report suspicious orders. In January 2017, McKesson entered into an agreement with the DEA in which they agreed to pay $150 million in settlement payments for failing to maintain effective controls against diversion of controlled substances. This specifically included the failure to report to the DEA suspicious orders of controlled substances. In May of 2012, Cardinal Health entered into an agreement with the DEA where they resolved allegations that they failed to maintain effective controls against the diversion of controlled substances by failing to detect and report suspicious orders relating to their distribution center in Lakeland, Florida, and in December of 2016, Cardinal Health agreed to pay a civil penalty of $34 million relating to this conduct. AmerisourceBergen has not yet paid any civil penalties to the DEA, but it has been subjected to similar allegations.

Manufacturer Defendants:

Manufacturers of opioids who may be responsible for damages to cities and counties include Purdue Pharma, Teva Pharmaceuticals, Janssen Pharmaceuticals, Endo Health Solutions, Cephalon, and Allergan. These companies are all in business of manufacturing opioid pain medication such as oxycodone, hydrocodone, or fentanyl.

In addition to failing to report suspicious orders of opioids, as detailed above, it is also widely documented that all of these entities played a role in increasing the consumer demand for

opioids by falsely advertising the risks of addiction associated with these drugs. In fact, Purdue Pharma has paid over $600 million in fines related to allegations of misbranding its best-selling drug, OxyContin.

Causes of Action:

Public Nuisance

There is no doubt that the overbearing presence of opioids plaguing cities and counties can be described as a public nuisance. The Restatement Second, Torts § 821B in part defines public nuisance as conduct that "involves a significant interference with the public health...." The conduct of the distributor and manufacturer defendants had a devastating effect on public health, safety and welfare and they should be required to fund the measures necessary to abate the nuisance.

Negligence

The distributors and manufacturers also face liability for negligence. The standard of care is established by the industry standards as outlined in HDMA's "Guidelines," the applicable federal statutes and regulations, and by related state law.

Distributors and manufacturers violated this standard of care by breaching their duty to identify and report suspicious opioid orders to the DEA or other relevant state agencies. There is no doubt that these violations directly contributed to the opioid epidemic that is running rampant across the nation, and without question, substantial damages have been incurred by cities and counties. These costs should be borne by the negligent distributor and manufacturer defendants.

Racketeer Influenced and Corrupt Organizations Act ("RICO")

As the curtain continues to be pulled back and more information becomes available on the distribution methods of opioid distributors and manufacturers, it becomes clearer that these entities were working hand-in-hand to maximize profits at the expense of the health and well-being of American citizens. The RICO statute is the perfect tool to expose these companies and their behavior, and to hold them accountable for the harm they have caused.

Conclusion:

The crack in the armor of the ARCOS database that began in West Virginia has revealed just how expansive the scope of the opiate epidemic is, as well as its origin. No one could have imagined how pervasive prescription opioids have become in our communities. We have devised a team of lawyers equipped to cut off the opioid supply at the source – the wholesale distributors and manufacturers - and to stop the infiltration of these drugs to your communities, and to help make a difference in U.S. cities and counties.

North Carolina-Specific Litigation Information

I. North Carolina Counties Have Standing to Hold Wholesale Opioid Distributors Accountable for Unlawful Distribution.

A. Nuisance Actions.

1. North Carolina Nuisance Law Specifically Imbues the Counties of North Carolina with Authority to Bring Claims.

The Counties of North Carolina are granted statutory authority to maintain a nuisance action for unlawful distribution of prescription drugs. Specifically:

> **Wherever a nuisance is kept, maintained, or exists**, as defined in this Article, the Attorney General, district attorney, **county**, municipality, or any private citizen of the county **may maintain a civil action in the name of the State of North Carolina to abate a nuisance under this Chapter, perpetually to enjoin all persons from maintaining the same, and to enjoin the use of any structure or thing adjudged to be a nuisance under this Chapter**; provided, however, that no private citizen may maintain such action where the alleged nuisance involves the illegal possession or sale of obscene or lewd matter.

N.C. Gen. Stat. Ann. § 19-2.1.

These provisions grant the North Carolina Counties standing to pursue a public nuisance action against wholesale drug distributors for violations of state and federal laws and regulations.

2. The Distribution of Opioids in Violation of North Carolina Laws Constitutes a Public Nuisance.

The unlawful distribution of opioids in violation of state and federal laws constitutes a nuisance under North Carolina law.

Under North Carolina law:

> (a) The erection, establishment, continuance, maintenance, use, ownership or leasing of any building or place for the purpose of [...] illegal possession or sale of controlled substances as defined in the North Carolina Controlled Substances Act, [...]. The activity sought to be abated need not be the sole purpose of the building or place in order for it to constitute a nuisance under this Chapter.
>
> (b) The erection, establishment, continuance, maintenance, use, ownership or leasing of any building or place wherein or whereon are carried on, conducted, or permitted repeated acts which create and constitute a breach of the peace shall constitute a nuisance.

N.C. Gen. Stat. Ann. § 19-1.

"Breach of the peace" is defined as "**repeated acts that disturb the public order *including, but not limited to***, homicide, assault, affray, communicating threats, unlawful possession of dangerous or deadly weapons, and discharging firearms." N.C. Gen. Stat. Ann. § 19-1.1. The statutory definition of "breach of the peace" includes crimes other than those listed. The North Carolina Court of Appeals has stated that "[a]lthough the definition is not confined to these examples, each individual example is a crime. Therefore, in order to determine if a breach of the peace has occurred, the nature of the incident will be determinative." *State ex rel. City of Salisbury v. Campbell*, 169 N.C. App. 829, 833, 610 S.E.2d 799, 801 (2005).

North Carolina statutes further provide as follows:

> A **wholesale drug distributor shall comply with applicable federal, State, and local laws and regulations.** A wholesale distributor that deals in controlled substances shall register with the federal Drug Enforcement Administration (DEA) and **shall comply with all applicable federal, State, and local laws and regulations**. A wholesale drug distributor is subject to any applicable federal, State, or local laws or regulations that relate to prescription drug salvaging or reprocessing.

N.C. Gen. Stat. Ann. § 106-145.10.

At common law in North Carolina, a public nuisance is defined by its consequences, and broadly includes "acts or conditions are subversive of public order, decency, or morals, or constitute an obstruction of public rights. Such nuisances always arise out of unlawful acts." *State v. Everhardt,* 203 N.C. 610, 617, 166 S.E. 738, 741-42 (1932).

> To constitute a public nuisance, the condition of things must be such as injuriously affects the community at large, and not merely one or even a very few individuals.... Whatever tends to endanger life, or generate disease, and affect the health of the community; whatever shocks the public morals and sense of decency; whatever shocks the religious feelings of the community, or tends to its discomfort-is generally, at common law, a public nuisance, and a crime.

Twitty v. State, 85 N.C.App. 42, 49, 354 S.E.2d 296, 301 (N.C.App.1987), *citing Everhardt*, 203 N.C. at 618, 166 S.E. at 742; *see also* Restatement (Second) of Torts § 82IB.

Critical circumstances, any one of which can create a public nuisance, include:

- significant interference with public health, safety, peace, comfort, or convenience,
- conduct contrary to a statute, ordinance, or regulation, or
- conduct in which the defendant continues to engage despite knowing, or having reason to know, of significant impairment of the public's rights.

See Restatement (Second) of Torts § 821B.

The opioid distributors have violated each of these tenets, as they have severely infringed public rights and interests, ensured continual circumvention of state and federal laws, and persisted in this conduct despite being aware of the terrible consequences. Those allegations state a public nuisance claim under North Carolina law.

3. Available Relief

Under North Carolina law Counties may seek injunctive relief in order to abate the opioid epidemic as a nuisance, including requiring the wholesale distributors to forfeit income earned through their unlawful activity.

> Upon judgment against the defendant or defendants in legal proceedings brought pursuant to this Article, an accounting shall be made by such defendant or defendants of all moneys received by them which have been declared to be a nuisance under this Article. **An amount equal to the sum of all moneys estimated to have been taken in as gross income from such unlawful commercial activity shall be forfeited to the general funds of the city and county governments wherein such activity took place, to be shared equally, as a forfeiture of the fruits of an unlawful enterprise, and as partial restitution for damages done to the public welfare**; provided, however, that no provision of this Article shall authorize the recovery of any moneys or gross income received from the sale of any book, magazine, or exhibition of any motion picture prior to the issuance of a preliminary injunction. Where the action is brought pursuant to this Article, special injury need not be proven, and the costs of abatement are a lien on both the real and personal property used in maintaining the nuisance. Costs of abatement include, but are not limited to, reasonable attorney's fees and court costs.

N.C. Gen. Stat. Ann. § 19-6.

B. Other Possible Causes of Action.

In addition to standing to pursue nuisance actions, the Counties may also have common law actions for negligence per se related to the distributors' violations of North Carolina statutes, for fraud, restitution or unjust enrichment.

Sample Of Key Documents

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Tuesday, July 11, 2017

Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations

Mallinckrodt LLC, a pharmaceutical manufacturer and one of the largest manufacturers of generic oxycodone, agreed to pay $35 million to settle allegations that it violated certain provisions of the Controlled Substances Act (CSA) that are subject to civil penalties, Attorney General Jeff Sessions of the Justice Department and Acting Administrator Chuck Rosenberg of the Drug Enforcement Administration (DEA) announced today.

This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone in Florida and elsewhere. The settlement also addressed violations in the company's manufacturing batch records at its plant in Hobart, New York. Both sets of alleged violations impact accountability for controlled substances, and the compliance terms going forward are designed to help protect against diversion of these substances at critical links in the controlled substance supply chain.

"In the midst of one of the worst drug abuse crises in American history, the Department of Justice has the responsibility to ensure that our drug laws are being enforced and to protect the American people," said Attorney General Sessions. "Part of that mission is holding drug manufacturers accountable for their actions. Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. Thanks to the hard work of our attorneys and law enforcement, Mallinckrodt has agreed to do everything they can to help us identify suspicious orders in the future. And as a result of today's settlement, we are sending a clear message to drug companies: this Department of Justice will hold you accountable for your legal obligations and we will enforce our laws. I believe that will prevent drug abuse, prevent new addictions from starting, and ultimately save lives."

"Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands," said DEA Acting Administrator Chuck Rosenberg. "When they violate their legal obligations, we will hold them accountable."

The government alleged that Mallinckrodt failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances – orders that are unusual in their frequency, size, or other patterns. From 2008 until 2011, the U.S. alleged, Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders. Through its investigation, the government learned that manufacturers of pharmaceuticals offer discounts, known as "chargebacks," based on sales to certain downstream customers. Distributors provide information on the downstream customer purchases to obtain the discount. The groundbreaking nature of the settlement involves requiring a manufacturer to utilize chargeback and similar data to monitor and report to DEA

suspicious sales of its oxycodone at the next level in the supply chain, typically sales from distributors to independent and small chain pharmacy and pain clinic customers.

The government also alleged that Mallinckrodt violated record keeping requirements at its manufacturing facility in upstate New York. Among other things, these violations created discrepancies between the actual number of tablets manufactured in a batch and the number of tablets Mallinckrodt reported on its records. Accurate reconciliation of records at the manufacturing stage is a critical first step in ensuring that controlled substances are accounted for properly through the supply chain.

In addition to the significant monetary penalty, this settlement includes a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious sales. The resolution advances the DEA's position that controlled substance manufacturers need to go beyond "know your customer" to use otherwise available company data to "know your customer's customer" to protect these potentially dangerous pharmaceuticals from getting into the wrong hands. DEA's Memorandum of Agreement with Mallinckrodt also sets forth specific procedures it will undertake to ensure the accuracy of batch records and protect loss of raw product in the manufacturing process.

By entering into these agreements, elements of which Mallinckrodt is already implementing, the company is becoming part of the solution to this public health epidemic.

This lengthy investigation was led by DEA's Detroit Field Division on the suspicious order issues and the New York Field Division on the manufacturing record keeping issues.

U.S. Attorneys' Offices for the Eastern District of Michigan and the Northern District of New York, along with DEA Office of Chief Counsel and Diversion Control Division, led the civil settlement negotiations. The Criminal Division's Narcotic and Dangerous Drug Section (NDDS) also coordinated and assisted in negotiating the settlement.

Component(s):
CriminalDivision
Drug Enforcement Administration (DEA)

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *el seq.,* ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425,

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AI W") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RMOI 73055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

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distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . effective controls against diversion of particular controlled substances," 21 U.S,C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Deiran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

En lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

1. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below, The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a, McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R, Part 1300 *et seg.,* at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306,04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

It. Terms and Conditions

Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations_

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances, This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkceping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to tile such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [itsj area of suspicious orders," 21 C.F,R. § 1301.74(h), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.govideareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM00 I /3425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List i Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan *48226,* a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (1) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section 11.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"), McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.,* administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

J. Any material breach by any McKesson facility of subsections II.l.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301,74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection IL1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

8. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a, and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement arid Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion,

5. Execution of Agreement. This Agreement shall become effective *(i.e.,* final and binding) on the date of signing by the last signatory (the "Effective Date"). The government *agrees* to notify McKesson immediately when the final signatory has executed this Agreement

6. Notices. Ail communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOI:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissctte Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisseuc Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 3& Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S, Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8, Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOTA"), 5 U.S.C, § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement,

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11, Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended,

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By Louis J. Milione for

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Cardinal Health, Inc., ("Cardinal") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Cardinal and all 28 Cardinal DEA registered distribution facilities.

BACKGROUND

1. Cardinal is registered with DEA at 28 facilities as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention Act of 1970, 21 U.S.C. § 801 et seq., ("CSA" or "the Act"). See Appendix A.

2. In September 2008, Cardinal entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA"). See Appendix B.

3. Cardinal's Lakeland distribution facility ("Cardinal Lakeland") is registered with DEA as a distributor of Schedule II-V controlled substances at 2045 Interstate Drive, Lakeland, Florida 33805, with an expiration date of May 31, 2012.

4. On February 2, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration to Cardinal Lakeland. See Appendix C.

5. The Order to Show Cause referenced above alleged, among other things, that:

   a. Despite the 2008 MOA, Cardinal Lakeland failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels as evidenced by sales to certain customers of Cardinal;

   b. Cardinal Lakeland failed to report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b); and

   c. Cardinal Lakeland failed to conduct meaningful due diligence of its retail pharmacies, including its retail chain pharmacy customers to ensure that controlled substances were not diverted into other than legitimate channels.

STIPULATION AND AGREEMENT

The facts alleged in the Order to Show Cause, as well as the facts alleged in the Government's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, constitute grounds under which DEA could revoke the DEA registration of Cardinal Lakeland. Cardinal admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate. In lieu of continuing proceedings to revoke the DEA registration of Cardinal Lakeland, Cardinal and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in this administrative matter is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters involving the conduct described in the Order to Show Cause, as well as DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D. The parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this administrative matter.

2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following:

a. Conduct alleged in the February 2, 2012 Order to Show Cause ("Order to Show Cause"), and in DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D;

b. Failure to maintain effective controls against the diversion of controlled substances, including failing to conduct meaningful due diligence to ensure that controlled substances were not diverted into other than legitimate channels, including failing to conduct site visits of its retail pharmacy chain customers on or before May 14, 2012;

c. Failure to detect and report suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b) on or before May 14, 2012; and

d. Failure to adhere to the provisions of the 2008 MOA, on or before May 14, 2012.

3. Effect of 2008 MOA. The obligations contained in the 2008 MOA are superseded by the obligations contained within this Agreement.

4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of Cardinal.

a. Cardinal agrees to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations. This program shall include procedures to review orders for controlled substances. Orders identified as suspicious will be reported to the DEA as discussed in subsection II.1.f. This compliance program shall apply to all current and future Cardinal distribution centers registered with the DEA in the United States and its territories and possessions. Cardinal acknowledges and agrees that the obligations undertaken in this Agreement do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.

b. Within 120 days of the Effective Date of this Agreement, for all states, excluding Florida, Cardinal will commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances that are known to be diverted, or should be known to be diverted, at the time of the orders that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted. For Florida pharmacies, retail and chain, Cardinal, within 20 days of the Effective Date of this Agreement, will commence these site visit procedures. Cardinal will also employ additional field inspectors to perform investigations of Florida pharmacies.

Cardinal will review and enhance its Quality and Regulatory Affairs ("QRA") processes and practices for establishing and increasing thresholds, including thresholds for Florida retail and chain pharmacies. Under the new processes and practices, two-person concurrence will be required before increasing thresholds for higher volume customers for specific drug classes. Cardinal understands that DEA does not endorse or otherwise approve threshold procedures, and that thresholds do not necessarily determine whether an order is suspicious.

c. Cardinal will create a Large Volume-Tactical and Analytical Committee to review and make decisions regarding higher-volume retail and chain pharmacy customers, including higher-volume pharmacies in Florida. The committee will include the SVP of QRA (chair), VP Supply Chain Integrity, Regulatory Counsel, and the Director of QRA Analytics or designated equivalent officers.

d. Cardinal will enhance existing processes and practices for conducting due diligence reviews of pharmacies, chain and retail, including those located in Florida.

e. On a monthly basis, Cardinal shall provide DEA Headquarters with a report of all sales transactions of controlled substances, as well as tramadol, through Electronic Data Interchange in a format mutually and reasonably agreed upon by the Parties. The data shall be due by the 15th of each month for the previous month's report. This information will be reconciled in the manner that Automation of Reports and Consolidated Orders System (ARCOS) data is reconciled. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for Cardinal's compliance with recordkeeping and reporting requirements under the CSA or applicable DEA regulations. The Parties agree that such report is not required under the CSA or DEA regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

f. Cardinal shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties, except that contrary to DEA regulations, Cardinal shall inform DEA Headquarters rather than the local DEA Field Office of suspicious orders, unless and until advised otherwise in writing by DEA Headquarters. DEA has previously notified all of the DEA Field Offices that Cardinal is not required to provide suspicious order reports or any other type of report regarding suspicious purchases of controlled substances to the DEA Field Offices. Execution of this Agreement by DEA shall waive the DEA regulatory requirements to report suspicious orders to DEA Field Offices for the duration of the Agreement.

g. Cardinal agrees to the continued suspension of its authority to handle controlled substances at Cardinal Lakeland until May 15, 2014, so long as the provisions of II.2.c are met.

h. Cardinal agrees that any express or implied approval by DEA of any previously implemented system to detect and report suspicious orders, is hereby rescinded and is of no legal effect with respect to Cardinal's obligations to detect and report suspicious orders in accordance with 21 C.F.R. § 1301.74(b).

i. Cardinal's policy and procedure is to cooperate with the government in any investigation. Cardinal agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting Cardinal's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of Cardinal in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by the DEA or other law enforcement

authorities. However, nothing in this paragraph shall be construed as a waiver by Cardinal or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

j. Any material breach by any Cardinal facility of subsections II.1.a-f of this Agreement by Cardinal after the Effective Date of this Agreement may be a basis upon which DEA can issue an Order to Show Cause seeking the revocation of Cardinal's DEA certificate of registration for that facility.

k. Cardinal agrees that it will dismiss, with prejudice, the pending appeal by Cardinal in Case No. 12-5061 as well as the pending petition for review by Cardinal in Case No. 12-1126 in the United States Court of Appeals for the District of Columbia Circuit. Cardinal agrees that it will also dismiss, with prejudice, Case No. 12-cv-185 in the United States District Court of the District of Columbia.

2. Obligations of DEA.

a. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) and as described in subsection II.1.g. of this Agreement. DEA agrees to waive the regulatory requirement to report suspicious orders of controlled substances to the DEA Field Offices.

b. In the event that DEA discovers information that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider Cardinal's entry into this Agreement; all actions taken by Cardinal pursuant to this Agreement; any remedial actions taken by Cardinal to address the alleged or perceived violative conduct; and the compliance history of Cardinal at the particular facility, and at other Cardinal facilities.

c. If Cardinal is in compliance with the terms of this Agreement, DEA agrees that it will take appropriate steps to lift the suspension of Cardinal Lakeland's DEA registration and, if needed, to grant any requisite registration renewal on May 14, 2014.

3. Joint Obligations of the Parties.

a. Cardinal and DEA agree that upon the execution of this Agreement, DEA and Cardinal shall file a joint motion with the DEA Administrative Law Judge to terminate all pending administrative proceedings against Cardinal Lakeland in *The Matter of Cardinal Health*, DEA Docket No. 12-32.

4. Release by DEA. (i) In consideration of the fulfillment of the obligations of Cardinal under this Agreement, DEA agrees to:

a. Release Cardinal, together with its subsidiary entities, distribution facilities, and registrants that are listed in Appendix A, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 for the conduct alleged in the Order to Show Cause, DEA's filings in *The Matter of Cardinal Health*, DEA Docket No. 12-32, as listed in Appendix D, and for the conduct alleged in this Agreement; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of May 14, 2012, and the review of the reports and records Cardinal submitted to DEA prior to May 14, 2012. This release applies only to administrative actions brought before or by the Agency.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-covered conduct. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct and DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. DEA expressly reserves the right to pursue civil action, through the United States Attorney's Office, against Cardinal for the "Covered Conduct" as described in this Agreement. At Cardinal's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming Cardinal is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

5. Release by Cardinal. Cardinal fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Cardinal has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Cardinal) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any liability other than administrative claims released in Paragraph II.4.a. and b.; or

c. Any liability based upon such obligations as are created by this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Cardinal, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Cardinal represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Cardinal further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices to Cardinal pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Cardinal providing written notification to DEA:

a. Gilberto Quintero, Senior Vice President, Supply Chain Integrity and Regulatory Operations, 7000 Cardinal Place, Dublin, Ohio 43017; fax: 614-757-6597; email: gilberto.quintero@cardinalhealth.com;

b. With copy to: Steve Falk, Executive Vice-President and General Counsel, 7000 Cardinal Place, Dublin, Ohio 43017, fax: 614-652-7325; email: steve.falk@cardinalhealth.com.

7. Disclosure. Cardinal and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

8. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

9. Authorizations. The individuals signing this Agreement on behalf of Cardinal represent and warrant that they are authorized by Cardinal to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

10. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Cardinal distribution facility at issue is located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the Controlled Substances Act.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of Cardinal Health:

_____
Craig S. Morford
Chief Legal and Compliance Officer

Dated:

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Michele M. Leonhart
Administrator,

Dated: 5/14/12

[redacted]

Dated: 5/14/12

Relevant Federal Statutes

21 U.S.C. § 842 (a) (5)

(a) Unlawful acts

It Shall be unlawful for any person -

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;

21 U.S.C. § 823 (b) (1)

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, research, or industrial channels;

21 C.F.R. § 1301.74 (b)

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Case No. 12-5061

CARDINAL HEALTH, INC.,
Plaintiff-Appellant,

v.

ERIC H. HOLDER, JR., *et al.*,
Defendant-Appellees.

On appeal from the United States District Court for the District of Columbia in
Case No. 1:12-cv-00185, Judge Reggie B. Walton

Appendix B
To *Amicus Curiae* Brief of the Healthcare Distribution Management Association "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances."

Industry Compliance Guidelines

HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION (HDMA) INDUSTRY COMPLIANCE GUIDELINES: REPORTING SUSPICIOUS ORDERS AND PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

Introduction

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines. Manufacturers, distributors, pharmacies and healthcare practitioners share a mission and responsibility to continuously monitor, protect and enhance the safety and security of this system to combat increasingly sophisticated criminals who attempt to breach the security of the legitimate supply chain.

The *HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances,* have been developed as part of HDMA member distributors' ongoing commitment to the safe and efficient distribution of all prescription medicines including controlled substances. These Industry Compliance Guidelines are consistent with, and further extend, the distributors' track record of supporting and implementing initiatives designed to improve the safety, security and integrity of the medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of Controlled Substances (CS) and the critical role of each member of the supply chain in helping to enhance security.

At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers. Due diligence can provide a greater level of assurance that those who purchase CS from distributors intend to dispense them for legally acceptable purposes. Such due diligence can reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach.

These Industry Compliance Guidelines can help identify facts and information about controlled substance product orders, and the customers placing the orders.

Healthcare Distribution Management Association (HDMA)
901 North Glebe Road, Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200
www.HealthcareDistribution.org

HDMA Healthcare Distribution Management Association

History

In 1970, Congress enacted into law the Controlled Substances Act (CSA) as part of Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides the Drug Enforcement Administration (DEA) within the Department of Justice (DOJ) with the authority to regulate the manufacture, importation, possession and distribution of certain drugs. An additional federal agency, the Food and Drug Administration (FDA), and individual states, regulate many other aspects of drug supply chain safety and security. The CSA also created a closed system of distribution for those authorized to handle CS. Since its enactment in 1970, the CSA has been amended several times, including by the following statutes:

- The Psychotropic Substances Act of 1978;
- The Controlled Substances Penalties Amendments Act of 1984;
- The Chemical Diversion and Trafficking Act of 1988;
- The Domestic Chemical Diversion and Control Act of 1993;
- The Federal Analog Act; and
- The Methamphetamine Precursor Control Act which was superseded by the Combat Methamphetamine Epidemic Act of 2005.

The regulations in Title 21, Code of Federal Regulations (C.F.R.) part 1300 to 1316 apply to all individuals and firms desiring to conduct business in CS. All such individuals and firms must be registered with DEA, and are required to maintain complete and accurate inventories and records of all transactions involving CS, as well as security for the storage of controlled substances. Additionally, Sections 823(b) and (d) of the CSA call for the maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

In addition, distributors are required by 21 C.F.R. § 1301.74(b) to report suspicious orders of CS:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. [Emphasis added.]

Distribution Industry Commitment to Prevent Diversion of CS

Although distributors have been required to identify and report "suspicious orders" of CS and listed chemicals, increasing concerns about the potential misuse of prescription CS have elevated awareness within the supply chain and have led to increased expectations by DEA. Therefore, HDMA developed these Industry Compliance Guidelines to further scrutinize purchase orders for these products. For example, in public statements to Congressional Committees, DEA has noted

the growing problem of diversion and abuse of controlled pharmaceuticals, and has indicated the agency is taking stronger measures to address this matter.[1]

With the strong endorsement and expertise of our members, the Healthcare Distribution Management Association (HDMA) has developed the following Industry Compliance Guidelines for preventing diversion and reporting suspicious orders. We believe that implementation of these guidelines will help ensure that CS are appropriately distributed to supply chain customers involved in the legitimate dispensing of these important pharmaceutical products to patients, and will help distributors identify possible diversion activities.

OUTLINE

The *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, contains the following elements:

I. Know Your Customer Due Diligence
II. Monitoring for Suspicious Orders
III. Suspend/Stop an Order of Interest Shipment
IV. Investigation of Orders of Interest
V. File Suspicious Order Reports With DEA
VI. Employees, Training and Standard Operating Procedures (SOPs)
VII. Additional Recommendations
Glossary of Abbreviations

[1] See testimony provided by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; December 13, 2005, July 26, 2006, September 18, 2007, and June 24, 2008; and by Michele M. Leonhart, Acting Administrator, Drug Enforcement Administration, United States Department of Justice, March 12, 2008.

I. KNOW YOUR CUSTOMER DUE DILIGENCE

a. Introduction

Before opening an account for a new customer, the distributor should (i) obtain background information on the customer and the customer's business; (ii) review that information carefully, and, where appropriate, verify the information; and (iii) independently investigate the potential customer. To help ensure that the Industry Compliance Guidelines remain robust and adaptable, the "Know Your Customer Due Diligence" phase also describes "Additional Recommendations and Documentation" containing further suggestions for managing the distributor's procedures.

A distributor may tailor this part of its customer evaluation procedure to the type of customer under review. If a distributor does so, it is recommended that the distributor categorize each potential customer according to the customer's DEA "Business Activity" type as indicated on the customer's DEA registration certificate; for example, Retail Pharmacy, Hospital/Clinic, Practitioner or Distributor.

The following steps are recommended.

b. Information Gathering

All information requested by a distributor should be provided by the owner of the potential customer, the pharmacist in charge; or, in the case of a non-pharmacy customer, an equivalent designee. Each completed application, questionnaire or other document providing information requested by the distributor from the potential customer should be signed by the potential customer's owner, pharmacist in charge or equivalent designee. The signature should be notarized or should be accompanied by the statement: "*I declare under penalty of perjury that the foregoing is true and correct. Executed on [date].*"

The information gathering step would include:

- Provide potential customer with a credit application;
- Provide potential customer with a background questionnaire requesting the following information:
  - Business background,
  - Customer base,
  - Average number of prescriptions filled each day,
  - Average number of CS item prescriptions filled each day,
  - Percentage of CS purchases compared to overall purchases,
  - Verification of physical security controls for CS storage,
  - Questions based on DEA guidance and communications,
  - Copies of all their state and federal licenses and registrations,
  - If the potential customer is not currently conducting Internet prescription fulfillment, certification that they are not doing so, and will notify the distributor before conducting Internet prescription fulfillment;

- If the potential customer is conducting Internet prescription fulfillment, obtain the following information from any potential customer utilizing the Internet to receive and fill prescriptions:
  - The date the potential customer began conducting Internet prescription fulfillment,
  - Products the potential customer expects to purchase,
  - The quantity of each product the potential customer expects to purchase,
  - Practitioners who will be writing prescriptions that will be filled by the potential customer, including each practitioner's DEA and state registration and license numbers, address, telephone number(s), and other relevant contact information, and
  - National Association of Boards of Pharmacy (NABP) Verified Internet Pharmacy Practice Sites (NABP VIPPS) check.
- Names of individuals authorized to sign DEA Form 222[2],
- A description of how the pharmacy/dispenser fulfills its corresponding responsibility to ensure that the prescriptions they receive are issued for a legitimate medical purpose (as required in 21 C.F.R. § 1306.04),
- Inspections:
  - Indicate whether DEA has audited/inspected the pharmacy/dispenser over a period of at least the last two (2) years and if so, explain why,
  - Indicate whether the pharmacy/dispenser has been inspected by the state regulatory/inspection authority such as the State Board of Pharmacy, and
- Identification of physicians and other treatment centers that are the potential customer's most frequent prescribers or highest purchasing doctors.

c. Information Review

After the information is received from the potential customer, it should be reviewed thoroughly. The review should include the following steps:

- Verify that the credit application is complete, and carefully review the information submitted;
- Verify that the customer background information supplied is complete, and carefully review the information submitted;
- Verify that the answers to the questions based on DEA guidance and communications are complete, and carefully review the information contained; and
- Verify the potential customer's state and federal licenses, registrations and CS schedule authorizations.

[2] See: 21 C.F.R. § 1301 regarding *"Orders for Schedule I and II Controlled Substances"* for DEA's regulations for ordering these products by means of either DEA Form 222 or electronically, including signature requirements.

d. Independent Investigation

The distributor should independently investigate the potential customer as follows:

- Check with the distributor's local DEA office for any information regarding the potential customer, such as DEA actions against the potential customer[3];
- Check with state oversight authorities, including the state Board of Pharmacy (for a potential pharmacy customer) and Board of Medicine (for a potential physician customer) to request further background information, such as state actions against the potential customer (some states may provide readily accessible information through the state's Web site);
- Check the DEA Web site and the Federal Register for any actions against the potential customer; and
- Conduct an Internet search to determine whether any potential Internet business can be identified as relating to the potential customer and whether there is any other relevant information that could affect the decision to do business with the potential customer.

e. Additional Recommendations and Documentation

It is recommended that:

- Individuals selected to develop questionnaires for part (a) and to conduct reviews and investigations under parts (b) and (c) above should receive appropriate training.
- The distributor should update the questionnaire(s) periodically, particularly if a concern arises during an investigation.
- The performance and results of all steps in the customer review process should be fully documented as to each potential customer, and such documentation should be retained in an appropriate file.
- After completing the steps outlined above, the reviewer of the potential customer should sign and date the information (in a designated location of the file) to indicate that the reviewer has conducted a thorough/complete review, and that the information contained in the file is accurate and complete to the best of his/her knowledge.
- A distributor may seek further information about a potential customer, including when the distributor determines that obtaining further background information, confirmation, or verification is warranted.
- The distributor may include provisions for notification of state and federal authorities of an unlawful activity identified under the "Know Your Customer Due Diligence" as required by local, state or federal law.

[3] Depending on the direction received from the local DEA office, the distributor may consider contacting the potential customer's local DEA office for further information regarding the potential customer.

II. MONITORING FOR SUSPICIOUS ORDERS

a. System Design

It is recommended that a distributor develop an electronic system, with accompanying written Standard Operating Procedures (SOPs), to meet the DEA's requirement in section 1301.74(b) that a distributor "design and operate a system to disclose to the registrant suspicious orders of controlled substances" (emphasis added). Distributors should assign responsibilities for identifying and investigating potentially suspicious orders, and for reporting suspicious orders. Specific elements of the monitoring system are further described below.

b. Identify Product and Customer Characteristics

Separate/classify/group customers into appropriate/different classes of trade. For example, retail pharmacies, hospitals, doctors, or dentists.

Separate the CS the distributor sells into groups or "families" of drugs (e.g., all CS items containing codeine). The following information may be useful for identifying the "families" of drugs:

- A distributor may use the DEA Web site to obtain DEA's designation of a drug's "controlled substance code number" to aid in developing a drug "family" for purposes of defining a threshold.[4]
  - (See: http://www.deadiversion.usdoj.gov/schedules/schedules.htm or http://www.usdoj.gov/dea/pubs/scheduling.html)
- Distributors may also use the National Technical Information Service (NTIS) system, which (i) identifies each individual CS Stock Keeping Unit (SKU) by National Drug Code (NDC) number, (ii) lists the active ingredient and (iii) lists the corresponding DEA controlled substance code number. The DEA controlled substance code number is set up by NDC number. An electronic copy of this information may be used to help identify the drug "families."
- Alternatively, a distributor may choose to identify "families" of drugs and track the dosage unit (e.g., tablet) order levels for each SKU.[5]
- A distributor should maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or new "Drugs of Concern" as the information is developed by the agency. Such new information should be made part of the identification of particular CS drugs or "families" to be monitored, as appropriate.

[4] For further information on the controlled substance code numbers, see 21 C.F.R. § 1308.03.
[5] This method may present implementation challenges due to of the different strengths of the drugs.

c. Develop "Thresholds" to Identify Orders of Interest

"Thresholds" for identifying orders of interest, *i.e.*, orders that warrant follow-up inquiry to determine whether they are suspicious, may be made by using averages shipped to a particular customer facility that are consistent with the class of customers to which the particular customer belongs. It is recommended that distributors develop such thresholds by calculating the average single order and the average monthly order per "family," per customer, and class of trade.

When evaluating thresholds, orders of "unusual size" and "unusual frequency" can be used to signal that an order may need further review. Distributors are also encouraged to structure their thresholds to support evaluation of whether the order deviates substantially from a normal pattern and/or is of unusual frequency. The following examples may aid in developing the thresholds:

- Patterns of ordering such as comparing the present order to:
  - past orders from the same customer (including the frequency of orders),
  - orders for extraordinary quantities outside of normal purchasing patterns typically followed by the customer or by other customers within the same class of trade, and
  - geographical area(s) of the country they service (e.g., orders from other establishments of the same type in the locale or region),
- Orders of more than one controlled substance that are known to be taken together (combinations) outside of normal prescribing and patient treatment practices, and
- DEA/State input.

Distributors are also encouraged to consider the following when developing "thresholds":

- Quantities of products the dispenser initially indicated during the "Know Your Customer Due Diligence" phase that it expected to purchase;
- A minimum of six months sales history and a maximum of 24 months sales history are recommended; Maintain contact with DEA through the local field office or the Office of Diversion Control's Web site, www.deadiversion.usdoj.gov, to ascertain changes in diversion patterns or emerging local or regional concerns; such new information may be used to adjust thresholds as appropriate; and
- Thresholds for all new customer accounts should be established at the lowest level indicated by information obtained during the "Know Your Customer Due Diligence" review.

d. Cumulative Reviews/Thresholds

A very important component of the system will be to include a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns. This would include, for example,

- A mechanism to compare percentages of orders for CS (individual products and/or "families") to orders of non-CS prescription drugs so as to identify a shift in a customer's business focus that may warrant further review.

- Determining if the purchaser's ordering pattern, for a period of several months, shifts in a manner inconsistent with their previous ordering patterns or inconsistent with the class of trade for that customer (e.g., a pharmacy that orders relatively few controlled substances over several months suddenly places a large order or several large orders in a concentrated period of time.)

e. Supplemental Mechanisms for Determining Orders of Interest

Distributors are encouraged to recognize that their methods for identifying an "Order of Interest" do not need to be limited to an electronic "threshold" system. Based on the distributors' knowledge of his/her customers, overall drug purchasing trends, information available from DEA and elsewhere, distributors are encouraged to allow for alternative criteria, in addition to those incorporated into the electronic system, to serve as indicators of an order of interest.

III. SUSPEND/STOP AN ORDER OF INTEREST SHIPMENT

If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest.

Ideally, the electronic system would contain a process to automatically "block" the order or otherwise stop the ordered product from being shipped. The distributor may, however, ship any non-CS included in the order and any other CS products as to which the order did not exceed a threshold or otherwise become characterized as an order of interest. A distributor may choose to report an order of interest to DEA immediately as a suspicious order or may first investigate the order as described in Section IV below and report it at the conclusion of the investigation if, but only if, it is determined to be a suspicious order.

IV. INVESTIGATION OF ORDERS OF INTEREST

a. Preliminary Steps

If a product order meets or exceeds a threshold, and is thereby identified as an order of interest (or on other grounds is characterized as an order of interest), it is recommended that the distributor examine the order further. The examination is intended to aid the distributor in reaching a decision to either ship product to fill the order or to continue to hold the order. Further examination will also aid in determining whether and when to report the order to DEA under 21 C.F.R. § 1301.74(b).

The drug or drugs that cause an order to become an order of interest should not be shipped to the customer placing the order while the order is an order of interest.

It is recommended that the distributor designate a person with suitable training and experience to investigate orders of interest.

b. Initial Review

When initially reviewing an order of interest, a distributor should first examine the specific drug code product order to determine whether the reasons the order met or exceeded the thresholds, or on other grounds was characterized as an order of interest, are not "suspicious" or whether the order warrants still further examination. The examination may include obtaining additional verification from the customer that placed the order. For example, the customer may be able to identify whether the order contained an error, or whether there has been a change in the customer's business circumstances that warrants a shift in its purchasing practices that can be readily identified.

c. Investigating the Order

If, after initial review, it is determined that the order should be examined further, it is recommended that the distributor conduct an additional review as quickly as possible. The following elements are recommended as part of the additional review:

Review prior orders
The distributor should review the customer's past purchasing history for trends/discrepancies to determine whether:

- The distributor had to investigate a prior order and the circumstance and results of any prior investigation, including whether a prior order exceeded the same or a different threshold, and how the present order compares to the past order(s) of interest;
- There has been an increase (or decrease) in orders for this "group" or "family" of CS products;
- There has been other unusual activity, such as "spikes" in prior orders (e.g., a pattern of ordering over several months where the customer has placed no orders, followed by a month with a large order);
- There has been a decrease in orders for other products, (potentially indicating a shift in focus or customer base);
- There has been a change in the customer's operating environment (e.g., a new medical establishment recently opened in the customer's neighborhood);
- There has been a change in availability of drugs (such as a new drug dosage form that has recently been approved by FDA) identified as a Drug of Concern by DEA's Office of Diversion Control; and
- There are end-of-year C-II quota issues.

Interview customer
Ask: Why is there an "unusual" order? What will you do with it? Who is prescribing it? (Who, what, when, where, why, how?)

Verify customer input – (where appropriate)
How and what information provided by the customer needs to be verified will be determined on a case-by-case basis, but examples of information that could be verified include:

- If a customer says there is a new medical establishment located nearby, verify the establishment's existence, name, address, practitioner(s) names and DEA registration numbers.
- If the customer says it called DEA, verify that it actually did so.
- If the customer states that a natural disaster destroyed its pharmacy and that it must restock, verify the disaster.
- If the customer claims it "lost" a shipment, verify the loss[6].

Additional Information
The distributor may seek additional information about the order and/or the customer who placed the order if, during the examination, it is determined that further confirmations or background information is warranted.

d. Documentation

All investigations should be fully documented, and all records of the investigation should be retained in an appropriate location within the firm (such as with other records relating to the particular customer).

At a minimum, documentation should include the name(s), titles(s) and other relevant identification of the representative of the customer contacted (e.g., "pharmacist in charge"), dates of contact, and a full description of questions asked and requests for information made by the distributor and of information provided by the customer. The documentation should include a clear statement of the final conclusion of the investigation, including why the order investigated was (or was not) determined to be "suspicious." That statement should be signed and dated by the reviewer. Copies of any written information provided by the customer should also be retained as part of the documentation of the investigation.

e. Shipment and Reporting Decisions (under 21 C.F.R. § 1301.74(b)); SOPs

At an appropriate point in the examination process, the distributor will decide how to resolve the order, specifically, whether the order is "suspicious," and should be reported. Employees should be selected and authorized to make shipment and reporting decisions based on their knowledge of DEA requirements, the distributor's business, customers and other relevant factors. (Further recommendations as to reporting to DEA can be found in Section V below.)

Orders that are determined to be "suspicious" should be reported to DEA under § 1301.74(b) immediately upon being so determined. It is assumed that the order will continue to be placed on

[6] Distributors should also determine whether there is an obligation to report the loss under 21 C.F.R. § 1301.76(b).

hold and/or cancelled, once it has been identified as "suspicious." An exception can be made if the distributor subsequently obtains additional or alternative information that leads to the conclusion that the order was misidentified as "suspicious," and/or is consistent with the pharmacy/dispenser's practice. In such instances, the order may be shipped. Full documentation of the reasons for the conclusion is recommended.

Each distributor is encouraged to develop SOPs that:

- Describe how an initial review and investigation will be conducted;
- Reflect the distributor's and its customers' business conditions;
- Are sufficiently flexible to adjust the review/investigation to address the individual product/order/customer circumstances that are likely to occur;
- Include a process and/or guidance/criteria for making the final determination that an order is, or is not, "suspicious";
- Define a process for reporting to DEA under 21 C.F.R. § 1301.74(b); and
- Define a process for allowing release of a shipment, or cancellation of an order, as appropriate.

f. Future Customer Orders

In instances where a distributor concludes that an order is (or remains) "suspicious" after conducting an investigation, in addition to notifying DEA, it is recommended that the distributor evaluate its business relationship with the customer that placed the order. The distributor may consider whether to subject future orders from the same customer for the same drug code product (or all CS) to more rigorous scrutiny than was applied before the determination that the order is suspicious. A distributor may also consider whether to cease filling all future orders of the drug code product (or all CS) placed by that customer.

V. FILE SUSPCIOUS ORDER REPORTS WITH DEA

a. Immediate DEA Notification

Under 21 C.F.R. § 1301.74(b), orders designated as "suspicious" must be reported to DEA "when discovered." Once the distributor has made the determination that an order is suspicious, a phone call to report the order to the local DEA office is recommended to meet this requirement (unless DEA provides other direction). The distributor should provide additional documentation to DEA upon request.

Additional considerations:

- Even if there is some ambiguity regarding a customer or an order's status, occasions may arise when the intended use of an order is questionable. For example, the distributor may identify information that leads them to believe that a potential customer, prior to entering a formal business arrangement with that customer, may

intend to order CS products with a frequency, volume or other indicator that could be considered "suspicious." In such instances, the distributor should provide DEA with a report of this information under 21 C.F.R. § 1301.74(b).

- Distributors are strongly encouraged to regard timeliness of reporting to DEA as a critical component in meeting the requirement to report "when discovered."

b. Correspondence for Reporting

It is recommended that all correspondence to DEA (containing reports of suspicious orders) should be sent registered mail with a return receipt requested, by electronic mail or by another system that creates for the distributor a permanent record that DEA has received the notification. Although correspondence to the local DEA office is encouraged as a follow-up to a telephonic notification, distributors are encouraged to discuss with the local DEA office whether that office prefers to receive a follow-up written notice and the form for such notice.

The cover letter for reports of suspicious orders may read: "This report is submitted to you in accordance with the requirements of 21 C.F.R. § 1301.74(b) and is for (company name)." When the return receipt is received, it should be stapled to the cover letter as proof of submittal. (It is suggested that the distributor title the report "21 C.F.R. § 1301.74(b)" report.)

In some states, additional reporting requirements may apply. Each distributor should determine whether a state report is required, and should comply accordingly.

It is recommended that the same person conduct the investigation, decide (perhaps in consultation with one or more superiors) whether or not to cancel the order, and also provide the report to DEA.

c. Documentation

All additional contact with DEA, either by telephone or in person, should be documented; and a record of the contact should be maintained.

VI. EMPLOYEES, TRAINING AND STANDARD OPERATING PROCEDURES

a. Employees/Training

Individuals working in CS areas should be screened and selected for their attention to detail, ability to recognize the importance of accuracy, length of tenure with the company and work ethic.

It is recommended that employee training:

- Include a review of DEA rules and regulations;
- Fully cover the firm's procedures for compliance;

- Include backup training to cover instances when the employee primarily responsible for monitoring for suspicious orders will not be available (e.g., due to vacation leave or sick leave); and
- Provide for periodic retraining.

It is recommended that training be conducted for all personnel involved in:

- Receiving, shipping, handling and record-keeping with respect to CS items;
- Sales, or in establishing new accounts and persons who interact with customers; and
- Reviewing, investigating and/or deciding whether to fill orders.

All such training should be documented, and the documentation should be maintained.

b. SOPs

It is recommended that, to implement these Industry Compliance Guidelines, specific written company SOPs be developed and maintained.

VII. ADDITIONAL RECOMMENDATIONS

It is recommended that a distributor include in its "system" provisions for:

- Periodic internal audits of suspicious orders, compliance procedures and results;
- Periodic reviews and revisions of internal SOPs for compliance with §§ 1301.71(a) and 1301.74(b) and new DEA guidance, as well as employee training requirements/procedures;
- Periodic review of the distributor's system for monitoring for suspicious orders, including the system design and the thresholds, to determine whether revisions should be developed. For example, if the FDA approves a new controlled substance, or a new indication for use of an existing controlled substance, or if DEA makes new information available regarding a Drug of Concern, revisions to the thresholds may be needed; and
- If appropriate, update customer and/or order records on the basis of information obtained while investigating an order under Section IV above.

Glossary of Abbreviations

	Abbreviation	Explanation of Term
	ARCOS	Automation of Reports and Consolidated Orders System
	C.F.R.	Code of Federal Regulations
	C-I, C-II, C-III, C-IV, C-V	References the DEA's designation of individual controlled substances into one of the five levels under 21 C.F.R. §1308
	CS	Controlled Substances has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.)
	CSA	Controlled Substances Act
	DEA	Drug Enforcement Administration
	DOJ	Department of Justice
	FDA	Food and Drug Administration
	HDMA	Healthcare Distribution Management Association
	NABP	National Association of Boards of Pharmacy
	NDC	National Drug Code
	NTIS	National Technical Information System
	SKU	Stock Keeping Unit
	VIPPS	Verified Internet Pharmacy Practice Sites

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

DBS TRADING INC
11930 KEMPER SPRINGS
CINCINNATI, OH 45240-0000

September 27, 2006

In reference to registration
RD0277409

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005); available at www.drugabuse.gov/PDF/RRPrescription.pdf

[2] 21 U.S.C. 801(2)

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

DEA-9 JA-892

Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. , ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 3

DEA-12

JA-895

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20537

MASTERS PHARMACEUTICAL, INC
11930 KEMPER SPRINGS
CINCINNATI OH, 45240-0000

December 27, 2007

In reference to registration
RD0277409

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 4

DEA-13 JA-896

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

In Re: Masters Pharmaceutical, Inc.
Docket No. 13-39
Government Exhibit 4

DEA-14 JA-897

Litigation Team

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BARON BUDD

Baron & Budd, P.C. is among the largest and most accomplished plaintiffs' law firms in the country. With 40 years of experience, Baron & Budd has the expertise and resources to handle complex litigation throughout the United States. As a law firm that takes pride in remaining at the forefront of litigation, Baron & Budd has spearheaded many significant cases for entities and individuals. Since the firm was founded in 1977, Baron & Budd has achieved substantial national acclaim for its work on cutting-edge litigation, trying hundreds of cases to verdict and settling tens of thousands of cases in areas of litigation as diverse as pharmaceuticals and defective medical devices, asbestos and mesothelioma, water contamination, fraudulent banking practices, motor vehicles, employment, and other consumer fraud issues.

Baron & Budd has represented hundreds of public entities in pharmaceutical, environmental, consumer and securities litigation. The Firm's attorneys were part of an attorney group that recently negotiated a $553 million settlement with 4 vehicle manufacturers regarding their use of faulty airbags manufactured by Takata. Baron & Budd's environmental litigation group litigated and settled claims on behalf of more than 150 water providers in 17 states regarding Methyl Teritary Butyl Ether (MTBE) contamination in groundwater. The $423 million settlement, reached with many of the country's leading gas companies, requires gasoline refiners to pay water providers' costs to remove MTBE from public drinking water wells and for refiners to pay for treatment of qualifying wells that may become contaminated within the next 30 years. The Firm's attorneys were co-lead counsel in litigation brought on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia; these cases settled for $177 million. Baron & Budd's environmental litigation group represented 30 mid-west water providers in litigation regarding the contamination of water systems by the agricultural chemical atrazine; these cases settled for $105 million. The firm also served as co-lead counsel for the states of West Virginia, Hawaii and Mississippi for their claims against various financial institutions regarding fraudulent marketing of payment protection plans and related credit card services, ultimately settling the cases for more than $43 million.

Baron & Budd represents thousands of individuals in pharmaceutical, defective medical device, securities, environmental and motor vehicle-related cases. The firm's attorneys have served or continue to serve on Plaintiffs Steering Committees and in key leadership roles in complex, multi-district litigations, including *In Re: 7-Eleven, Inc. Shareholders Litigation*; *In re Semtech Corporation Securities Litigation*; *In Re: Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation*; *In Re: Checking Account Overdraft Litigation*; *In Re: Oil Spill by the Oil Rig Deepwater Horizon in the Gulf of Mexico*; the 7 Pelvic Repair System Products Liability MDLs; *In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation*; *In re: Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Products Liability Litigation*; *In Re: Bard IVC Filters Products Liability Litigation*; *In Re: Takata Airbag Products Liability Litigation*; *In Re: Fluoroquinolone Products Liability Litigation*; *In Re: Zofran (Ondansetron) Products Liability Litigation*; and *In Re: Volkswagen Clean Diesel Marketing, Sales Practices, and Products Liability Litigation*.

Baron & Budd's attorneys are consistently recognized for excellence in advocacy by both peers and national legal publications and organizations, including the *Best Lawyers in America*, *National Trial Lawyers Top 100 Trial Lawyers List*, and the Firm's attorneys won a 2017 Burton Award, recognizing outstanding legal writing for an article appearing in *Trial* Magazine. *The National Law Journal* has included the firm in its NLJ "Hot List" of exemplary plaintiffs firms in the United States eight years since the list's inception in 2002 (American Lawyer Media). *The National Law Journal* also named Baron & Budd to the list of America's Elite Trial Lawyers, a list is comprised of 50 law firms that have achieved significant results on behalf of plaintiffs within the previous year and have an established track record of delivering impressive results. Baron & Budd has been a finalist for the Public Justice Foundation's "Trial Lawyer of the Year" award four times – most recently in 2013 for the Atrazine litigation and 2012 for the *In Re Checking Account Overdraft Litigation* – and was awarded the honor in 2007 for its work on a decades-long case against fighting water contamination in Tucson, Arizona.

Baron & Budd has frequently contributed resources and finances to a number of worthwhile nonprofit organizations including the International Mesothelioma Program at Brigham and Women's Hospital, Asbestos Disease Awareness Organization, Lung Cancer Alliance, the National Comprehensive Cancer Network (NCCN), Attorneys Serving the Community (a Dallas-Ft. Worth area women's attorney group), Genesis Women's Shelter and the Dallas Children's Advocacy Center.

BARON BUDD

Russell W. Budd, a shareholder of Baron & Budd since 1985 and president and managing shareholder since 2002, has devoted his entire career to championing the rights of people and communities harmed by corporate malfeasance. As chair and member of several asbestos creditors' bankruptcy committees, Budd has successfully resolved over 100,000 victims' claims with some of Wall Street's biggest companies, including establishing trust funds and settlement funds valued at nearly $11 billion to protect present and future asbestos victims throughout the United States.

Budd has also been instrumental in conducting national negotiations for non-asbestos claims. Budd was a leader in settlement negotiations in *In Re Checking Account Overdraft Litigation* that resulted in settlements valued at more than $500 million in cash and more than $100 million in business practice changes. Budd was one of the negotiators of a $177 million settlement for litigation brought on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia, and was a key negotiator of settlements valued at more than $43 million for the states of West Virginia, Hawaii and Mississippi for their claims against various financial institutions regarding fraudulent marketing of payment protection plans and related credit card services.

Baron & Budd shareholder Burton LeBlanc has successfully represented both individuals and governmental entities, including the States of Hawaii, Mississippi, Louisiana, and West Virginia in complex consumer fraud litigation. He was part of Baron & Budd's team that pursued litigation on behalf of seven states' attorneys general against GlaxoSmithKline regarding its fraudulent marketing of the diabetes drug Avandia, litigation which settled for $177 million. LeBlanc is a recent (2013-2014) past-president of the nation's largest non-profit trial lawyer group, American Association for Justice (AAJ). He remains actively involved with AAJ and shares their commitment to relentlessly advocate for the protection of America's civil justice system and the fundamental right to a trial by jury. LeBlanc is a 2017 recipient of the Lifetime Achievement Honor from America's Top 100 Attorneys for his career dedicated to the protection of America's civil justice system. He was named as one of the top 75 plaintiff's attorneys in the United States by *The American Lawyer* in 2014 and has also been selected for inclusion in the *Louisiana Super Lawyers*® list from 2012 to the present.

Roland Tellis' practice focuses on complex, high-profile litigation, including consumer class actions, financial fraud, business torts, corporate misconduct, automobile defect, food labeling, false advertising, securities fraud and environmental contamination. He holds leadership roles in numerous multi-state, complex class action cases, including *Bias v. Wells Fargo Bank*, a certified nationwide RICO class action involving millions of mortgage loans that settled for more than $50 million; *In re: Volkswagen "Clean Diesel" Marketing, Sales Practices, and Products Liability Litigation*, a multi-state class action in the process of settling with values and fines totaling in the billions of dollars, involving hundreds of thousands of vehicles equipped with "defeat devices" designed to evade emissions laws; and *In Re: Takata Airbag Products Liability Litigation*, which has received preliminary approval for a settlement valued at $553 million. Tellis received commendation from the U.S. Department of Justice and the Federal Bureau of Investigation for his assistance in a successful parallel prosecution of a $120 million securities Ponzi scheme perpetrated by foreign currency traders. He has served on the Board of Governors of the Association of Business Trial Lawyers and as a Lawyer Representative to the Ninth Circuit Judicial Conference. Tellis has also served as a Co-Chair of the Settlement Panel of the U.S. District Court for the Central District of California. He was selected for the 2017 edition of *The Best Lawyers in America*®.

Former Baron & Budd Shareholder S. Ann Saucer is an Of Counsel lawyer with the firm, focusing her practice on appellate advocacy and briefing in complex litigation for both individuals and public entities. She has successfully argued before the U.S. Fifth Circuit Court of Appeals, the U.S. Ninth Circuit Court of Appeals, the Texas Court of Appeals (Dallas) and federal and state trial courts across the country, often as the key author of briefings and presenter of oral argument. Ms. Saucer has also spoken and published articles on federal procedure issues. Her background covers the spectrum of commercial, financial, pharmaceutical and defective medical devices, environmental law, consumer protection, product liability and toxic torts.

LEVIN PAPANTONIO
Thomas · Mitchell · Rafferty · Proctor · P.A.

Levin Papantonio was founded in 1955, in Pensacola, Florida, and is one of the largest plaintiff's law firms in the country with nearly 40 attorneys and more than 150 support staff.

Levin Papantonio has a longstanding reputation as one of America's premier trial firms. Levin Papantonio attorneys have tried more than 150 cases resulting in jury verdicts exceeding $1 million, and the firm has recovered more than $3 billion through verdicts and settlements over the last 25 years. The National Law Journal recognized Levin Papantonio as the fourth most successful law firm in America based on total jury verdicts in 2002. Fred Levin was named one of the nation's "Top Ten Litigators." After securing a $380 million verdict in 2007, three of the firm's attorneys were nominated as one of the top trial teams in the country by the Public Justice Foundation. Through multiple trial verdicts against Dupont regarding C8, Levin Papantonio lead a $920 million settlement in 2017. Over 60 years, Levin Papantonio attorneys have been committed to aggressively pursuing our clients' rights through trial.

Levin Papantonio routinely holds leadership positions in some of the country's most complex multi-district litigations, including the Plaintiffs' Executive Committee for In re Deepwater Horizon (BP) Oil Spill in the Gulf, MDL 2179 (E.D. LA), helping to bring about the recent $20.8 billion settlement in that action. The firm's attorneys also served on the Plaintiff Steering Committee and as co-chair of the Discovery Committee for the Bayer Yaz/Yasmin pharmaceutical litigation, in which Bayer has paid approximately $2 billion to date. Levin Papantonio has decades of leadership experience spearheading America's most complex litigation. Levin Papantonio routinely represents cities, counties, and government agencies in lead counsel roles ranging from areas such as pharmaceutical, environmental, derivative, securities, and antitrust litigation, to a key role in the landmark tobacco cases brought by states to recover health care expenditures.

Levin Papantonio is "AV" rated, and its attorneys have been inducted into the National Trial Lawyer Hall of Fame, listed in Best Lawyers in America, and profiled by national publications and news outlets including the New York Times, Los Angeles Times, Forbes, Time Magazine, Newsweek, Fox News, ABC News, and CNN. The attorneys at Levin Papantonio have the experience and resources necessary to hold large corporations accountable for their wrongful conduct. As a nationally recognized litigation firm, Levin Papantonio has built a reputation on its willingness to litigate to verdict complex disputes against some of the world's largest companies.

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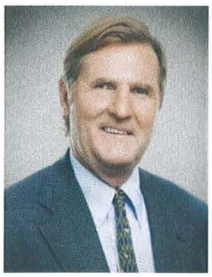

Mike Papantonio is a senior partner of Levin Papantonio and is a Board Certified Civil Trial Lawyer by the Florida Bar and the National Board of Trial Advocacy. He is a member and leader of both national and international legal associations, including the National Trial Lawyers Association, of which he was the 2012 President.

Mr. Papantonio is recognized as one of the Best Lawyers in America and a Leading American Attorney, was awarded the Florida Justice Association 2011 Perry Nichols Award, and has been selected by the Public Justice Foundation as a finalist for its Trial Lawyer of the Year Award. Mr. Papantonio also founded Mass Torts Made Perfect, which has trained thousands of lawyers in how to better their legal practice, and featured speakers including United States Presidents.

Mr. Papantonio has obtained multiple settlements and verdicts in the tens and hundreds of millions of dollars. In 2001, Mr. Papantonio obtained a $70 million settlement against polluters of waterways. In 2007, as lead trial counsel in an environmental class action Mr. Papantonio received a jury verdict award for a West Virginia community with an estimated value in excess of $380 million. In 2017, he helped secure a $920 million DuPont C8 settlement.

Peter Mougey is a shareholder and the Chair of Levin Papantonio's Securities and Business Litigation department. Recognized as one of Florida's top 100 trial lawyers, a Florida Super Lawyer in securities litigation, Mr. Mougey has been rated AV Preeminent through Martindale-Hubbell and has served as the president of the international securities bar association PIABA ("Public Investors Arbitration Bar Association") and on the Board of Directors and Executive Committees thereof.

In Mr. Mougey's securities and complex litigation practice, over the last five years, Mr. Mougey has represented approximately 50 state, municipal, and institutional clients in litigation and arbitration, as well more than one thousand fraud victims in state and federal court and arbitrations across the country. He has recovered more than $250 million on behalf of his clients.

A founding member of the Business Torts section of Mass Torts Made Perfect, Mr. Mougey is a frequent national speaker regarding issues related to complex litigation. Mr. Mougey also serves in leadership positions in local community organizations and charities, including as President of the Association of Retarded Citizens ("ARC").

Mark Proctor is the president of Levin Papantonio, leading the firm in its large-scale, complex litigation. Under Mr. Proctor's leadership, Levin Papantonio has secured billions of dollars in recoveries for clients. Mr. Proctor's extensive experience includes serving as former Assistant General Counsel for the City of Jacksonville, and the former General Counsel for the State of Florida Department of Natural Resources.

Mr. Proctor has served as a member and in leadership roles in the Florida Bar Association, the Florida Justice Association, the American Association of Justice, and the National Trial Lawyers Association. He is a founding member of Mass Torts Made Perfect, is a member of the Board of Trustees of the Fredric G. Levin College of Law at the University of Florida, and also serves on the board of directors for several charitable organizations. An author of seminal environmental articles for the Center of Land Use Law, Mr. Proctor has also been an adjunct professor of Environmental Law at the University of Florida and the University of West Florida.

Laura Sherling Dunning is an attorney in the Securities and Business Litigation department of Levin Papantonio. Mrs. Dunning has been repeatedly recognized as an Alabama and MidSouth Super Lawyer Rising Star in securities litigation. In her practice, which focuses on complex business litigation, whistleblower, class action, and antitrust litigation, Mrs. Dunning has represented dozens of governmental entities and hundreds of fraud victims in arbitration and in state and federal court, and has helped secure more than one hundred million dollars in recoveries for clients. Mrs. Dunning also serves in leadership positions with local charitable boards.

Archie Lamb is a nationally recognized leader in national healthcare and physician issues, and serves as of-counsel with Levin Papantonio. Mr. Lamb was the designated lead counsel in the massive HMO RICO lawsuit, where he, as lead negotiator in the HMO cases, successfully resolved the claims with benefits to the class estimated to exceed $2 billion. The case included over 60 healthcare companies, and Mr. Lamb was responsible for overseeing 26 law firms and over 170 lawyers in the litigation.

The first recipient of the California Medical Association's prestigious President's Award, Archie is a sought after speaker on legal issues facing healthcare professionals. He has appeared before the American Medical Association, numerous state and local medical associations, bar groups, and legal and medical educational seminars, as well as on CNN and National Public Radio. He is a frequent contributor to business and legal publications in the area of healthcare law.

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GREENE KETCHUM

FARRELL BAILEY & TWEEL LLP

Personal Injury Attorneys

For 60 years, Greene, Ketchum, Farrell, Bailey & Tweel LLP has been committed to fighting for justice for their clients, and has been a highly esteemed pillar in the community. The firm's attorneys have served on numerous legal and educational boards in West Virginia, including West Virginia State Bar Board of Governors; the West Virginia Ethics Commission; West Virginia Law Institute's Governing Council; West Virginia Judicial Vacancy Advisory Commission; West Virginia Association for Justice Board of Governors; Marshall University Foundation, Inc.; The Society of Yeager Scholars at Marshall University; the Faculty Merit Foundation of West Virginia, Inc. (selects higher education's "Professor of the Year"); the Marshall University Graduate School Advisory Board; Hospice of Huntington; and the Cabell County American Cancer Society.

Greene Ketchum attorneys have successfully tried numerous civil cases to verdict in state and federal courts. Their skilled advocacy has returned millions of dollars in verdicts for their clients in both trial settings and settlements. The firm's attorneys have been recognized by legal organizations for excellence and included in The National Advocates Top 100 Trial Lawyers and West Virginia Super Lawyers®.

Paul Farrell, Jr. is a West Virginia trial lawyer and partner at Greene, Ketchum, Farrell, Bailey & Tweel, LLP in Huntington, West Virginia. Mr. Farrell is recognized as a premier trial lawyer in the field of medical malpractice and appellate advocacy, making some thirty (30) appearances before the West Virginia Supreme Court. He has been a frequent presenter at legal education seminars and since 2004 has served on the West Virginia Continuing Legal Education Commission.

Mr. Farrell filed some of the first transvaginal mesh (TVM) cases in the country and served as liaison counsel on the executive committee for the 7 Pelvic Repair System Products Liability MDLs in Charleston, West Virginia. These MDLs consolidated 80,000 cases and resulted in several multi-million dollar jury verdicts. Mr. Farrell served as trial counsel for the TVM litigation, successfully trying 2 bellwether cases to verdicts in excess of $20 million.

Mr. Farrell recently filed the first cases in the country on behalf of public entities against the wholesale distributors of prescription opiates in southern West Virginia and is focusing his efforts to abate the nationwide opioid epidemic.

Mr. Farrell is a graduate of the University of Notre Dame (1994) and West Virginia University College of Law (1997) and licensed to practice law in West Virginia, Ohio and Kentucky. He was named West Virginia Association for Justice Trial Lawyer of the Year (2002) and served as the President of the West Virginia Association for Justice (2011-2012).

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HPCB&D Hill, Peterson, Carper, Bee & Deitzler, PLLC

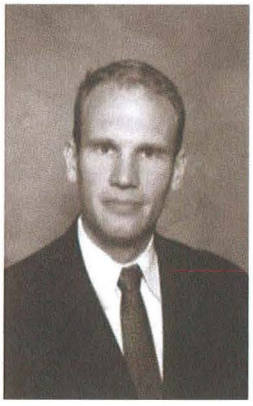
The Law Firm of Hill, Peterson, Carper, Bee & Deitzler, PLLC, began in 1980, when senior partner, R. Edison Hill, departed a large corporate and insurance defense firm to begin a small personal injury practice. The firm's attorneys represent individuals and families in many diverse areas of complex litigation including water contamination, personal injury, pharmaceutical and defective medical devices, and medical malpractice. The firm's attorneys were awarded the prestigious Trial Lawyer of the Year award by Public Justice in 2005 for their work on the successful class action litigation *Leach, et al. v. E. I. du Pont de Nemours and Company* involving representation of plaintiffs who suffered various cancers and other illnesses due to exposure through drinking water to the chemical ammonium perfluorooctanoate ("PFOA" or "C-8"), a chemical utilized in the manufacture of Teflon. The firm's attorneys also served on the Plaintiffs Steering Committee for *In re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, which has reached a global settlement of close to $1 billion. Hill, Peterson, Carper, Bee & Deitzler, PLLC, has been designated by "Benchmark Plaintiff" (The Definitive Guide To American Leading Plaintiff Firms & Attorneys) as one of West Virginia's three top and "highly recommended" litigation law firms.

R. Edison (Ed) Hill is a trial attorney and the founder and a member/partner of Hill, Peterson, Carper, Bee & Deitzler, PLLC. Mr. Hill has served as class action counsel for numerous certified class actions, including *Burch, et al. v. American Home Products Corp, et al.* (Fen-Phen Diet Drug Litigation), the largest pharmaceutical class action in the history of West Virginia, and *Leach, et al. v. E. I. du Pont de Nemours and Company.* He also serves on the Plaintiffs Steering Committee for *In re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, which recently reached a settlement valued at nearly $1 billion. Mr. Hill was named as one of "America's 100 Most Influential Trial Lawyers" by *The Trial Lawyer*'s RoundTable in 2017 and has been designated as one of West Virginia's twelve "Litigation Stars" by *Benchmark Plaintiff* (The Definitive Guide To American Leading Plaintiff Firms & Attorneys). He has also been named as a Fellow of the West Virginia Bar Foundation, awarded to "lawyers whose professional, public and private careers have demonstrated outstanding dedication to the welfare of their communities and honorable service to the legal profession with the individuals selected reflecting the diverse nature of the legal profession in West Virginia." Mr. Hill is involved in many legal professional organizations, including American Association for Justice (Life Member), National Trial Lawyers Association (Executive Committee Member), West Virginia Trial Lawyers Association (Past-President and current Board of Governors member), Public Justice Foundation, Lawyer-Pilots Bar Association, Southern Trial Lawyers Association and the Consumer Attorneys of West Virginia. He has been named a *West Virginia Super Lawyer*® each year from 2009 the present. He also serves as Chairman for the Central West Virginia Regional Airport Authority, which is the governing board for Yeager Airport, located in Charleston, West Virginia. He has served on the Yeager Airport Board of Directors since 1993.

James C. Peterson has been a member/partner at Hill, Peterson, Carper, Bee & Deitzler, PLLC since 1983, focusing his legal practice on litigation of severe personal injury, medical/legal malpractice, product liability, insurance bad faith, mass tort/class action involving defective products, pharmaceuticals and insurance issues. He served as co-lead counsel for the settlement of the largest pharmaceutical class action litigation in the history of the State of West Virginia, involving the diet drug Fen-Phen (*Burch, et al. v. American Home Products Corporation, et al.*). Settlements and verdicts handled on behalf of Hill & Peterson or on a co-counsel basis exceeds $1.6 billion. Representative mass tort/class action in addition to *Burch* includes *McCallister, et al., v. Purdue-Pharma, Inc., et al.* (Oxycontin - potent pain killer drug); *VIOXX Products Liability Litigation*, MDL 1657 (osteo-arthritic pain medication); *In Re: E. I. Dupont de Nemours and Company C-8 Personal Injury Litigation*, MDL 2433 (involving representation of 3,500 plaintiffs who suffered various cancers and other illnesses due to exposure to C-8, a chemical used in the manufacture of Teflon, in public drinking water; global settlement reached in 2017 for close to $1 billion.); and *Good v. American Water Works Company, Inc.*, et al., Case No. 2:14-CV-01374 (putative class alleging economic and personal injury loss due to water contamination, tentative settlement reached Fall 2016, for over 250,000 residents and businesses in the 9-county area). Mr. Peterson has been board-certified as a civil trial specialist by the National Board of Trial Advocacy (NBTA) since 1990; named member of the year by the West Virginia Trial Lawyers Association in both 1988 and 1993; served in a variety of positions with both state and national trial lawyer organizations, including president of the West Virginia Trial Lawyers' Association (1996-1997); and admitted to practice in the states of Minnesota, Ohio, and West Virginia. Since 1987, Mr. Peterson has presented over 40 papers and articles nationwide on various legal topics in over two dozen states. He authored a chapter for a National Brain Injury Association publication involving hedonic damages, and an article on the same for TRIAL Magazine (published by American Association for Justice). Mr. Peterson is recognized as a life member of American Association for Justice (AAJ), an honor bestowed on approximately 50 lawyers for that nationwide trial organization. He was selected in 2005, along with two of his partners Ed Hill and Harry Deitzler, as Trial Lawyers of the Year by Public Justice.

McHUGH FULLER LAW GROUP

McHugh Fuller Law Group is a trial firm based out of Hattiesburg, Mississippi that specializes in complex litigation and trials in the health and medical fields. With only eight members, the firm functions as an elite trial team made up of experienced litigators and legal writers. The attorneys at McHugh Fuller are admitted to practice law in eighteen states including Mississippi, Florida, Texas, Alabama, Arkansas, Georgia, Illinois, Kentucky, Michigan, Missouri, New Hampshire, New York, Ohio, Oklahoma, Pennsylvania, Tennessee, West Virginia, Wisconsin, and the District of Columbia. Our lawyers have tried over one hundred cases, obtaining multi-million dollar verdicts in courts throughout the country. The attorneys at McHugh Fuller have amassed over three-hundred million dollars in jury verdicts alone, and have successfully handled appeals before State Supreme Courts and Courts of Appeal in seven states, numerous Federal District Courts, the 4th, 5th and 11th Circuit Courts of Appeal and the United States Supreme Court.



Mike Fuller has extensive experience in nursing home, medical malpractice and criminal prosecutions and trials. He has worked with a top national law firm and the Hillsborough County State Attorney's Office in Florida, and he has litigated and tried numerous cases to verdict in jurisdictions nationwide.

Mr. Fuller obtained his undergraduate degree from the University of Central Florida, where he graduated Summa Cum Laude, and his Juris Doctorate from the University of Florida, where he graduated with high honors. Part of his educational process was spent working in the White House as an intern involved with Presidential Correspondence, providing a wealth of experience with citizens, legislators and diplomats across the United States.

Mr. Fuller is licensed to practice law in the District of Columbia, Florida, Georgia, Kentucky, Michigan, Mississippi, Missouri, New York, Ohio, Pennsylvania, Tennessee, West Virginia and Wisconsin.

Amy Quezon received her undergraduate degree from Furman University in 1989. She received her Juris Doctorate degree from Stetson University, College of Law, cum laude, in 1992.

Prior to joining McHugh Fuller Law Group, Ms. Quezon was an associate with the law firm of Jacobs & Goodman. Prior to that she was with the law firm of Wilkes & McHugh, P.A. where she practiced nursing home abuse and neglect litigation. Ms. Quezon also spent part of her career as a prosecutor with the Hillsborough County State Attorney's Office. While there, Ms. Quezon was the lead trial attorney focusing on violent felony cases. During her career, she has tried over 100 civil and criminal jury trials.

Ms. Quezon is licensed to practice law in Florida, Georgia, Kentucky, Mississippi, Missouri, New Hampshire, Ohio, Tennessee, Texas, West Virginia and Wisconsin. She is a member of the Florida Bar, the Hillsborough County Bar Association, The Florida Justice Association (f/k/a The Academy of Florida Trial Lawyers), the American Bar Association, the American Association for Justice (f/k/a the American Trial Lawyers Association), the Mississippi Bar Association, the State Bar of Texas, and the Southern Trial Lawyers Association.

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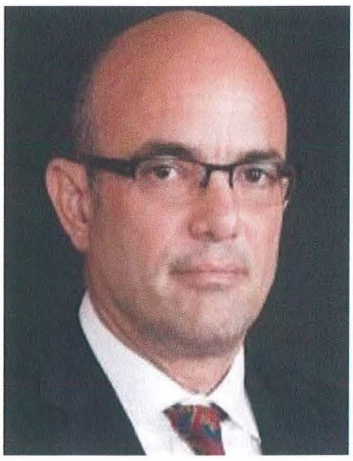
POWELL & MAJESTRO PLLC

ATTORNEYS AT LAW



Founded in 2002, Powell & Majestro, P.L.L.C. has been a premier resource for clients who want experienced, dynamic legal representation. With more than 55 years of combined experience, Powell & Majestro attorneys are nationally recognized for their work in serious injury claims. Powell & Majestro attorneys have successfully tried numerous civil cases to verdict in state and federal courts. Their skilled advocacy has returned recoveries totaling hundreds of millions of dollars in settlements and verdicts for clients.

Anthony J. Majestro is the Managing Member of Powell & Majestro, PLLC. Mr. Majestro concentrates his practice in prosecuting complex litigation, focusing on consumer fraud and defective products, including defective drugs and medical devices. In the course of his practice, Mr. Majestro has served as class counsel, lead counsel, liaison counsel and in leadership roles in a number of state and national class actions, mass torts, and other complex cases. Mr. Majestro has developed an extensive appellate practice and has numerous appellate victories in state and federal appellate courts across the country, including a unanimous decision on the merits from Supreme Court of the United States. Mr. Majestro regularly serves as appellate counsel and also represents state and local officials and agencies in trial and appellate litigation. Most recently he was lead appellate counsel in the successful defense of the plaintiff's verdict in the first bellwether trial in the vaginal mesh M.D.L. *Cisson v. C. R. Bard, Inc.* (4th Cir. 2016).

Mr. Majestro was the President of the West Virginia Association for Justice from 2013 – 2014. He has served as a member of the WVAJ Board of Governors for more than a decade and has been a member of the organization's executive committee since 2007. He was named the West Virginia Association for Justice's Member of the Year in 2007 and 2012. He is one of the founding co-chairs of the American Bar Association's Committee on Attorney Generals. Mr. Majestro regularly lectures at state and national seminars on topics related to law office automation, consumer protection, class actions, appellate litigation, and mass torts.

Mr. Majestro is a *summa cum laude* graduate of West Virginia University (1986) and a *cum laude* graduate of Georgetown University Law Center (1989) and is licensed to practice law in West Virginia and various federal district and appellate courts. Mr. Majestro was selected as a Harry S. Truman Scholar and served as a law clerk to the Honorable Thomas A. Clark of the United States Court of Appeals for the Eleventh Circuit in Atlanta, Georgia.

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[DATE]

VIA EMAIL

[NAME OF COUNTY]

RE: ***Engagement of Simmons Hanly Conroy LLC, Crueger Dickinson LLC, and von Briesen & Roper, s.c. as Counsel in Relation to Claims Against Opioid Manufacturers***

Dear [NAME OF COUNTY]:

The purpose of this letter ("Engagement Letter") is to set out in writing the terms and conditions upon which the law firms of Simmons Hanly Conroy LLC, Crueger Dickinson LLC and von Briesen & Roper, s.c., (collectively "Counsel) will provide legal services to [NAME OF COUNTY] ("County") in relation to the investigation and prosecution of certain claims against the following manufacturers and other parties involved with the manufacture of opioid medications: Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., OrthoMcNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc., Endo Pharmaceuticals, Inc. (collectively "Opioid Manufacturers"). Depending upon the results of initial investigations of the facts and circumstances surrounding the potential claim(s), there may be additional parties sought to be made responsible and/or certain of the aforementioned parties may be removed from the potential claim.

This Engagement Letter shall apply solely and exclusively to the services set forth herein in relation to the investigation and Lawsuit, as defined below. This Engagement Letter does not govern, nor does it apply to, any services of either Counsel unrelated thereto.

SCOPE OF SERVICES

Counsel will work with County in the collection of information necessary to form a good faith basis for filing a claim against the Opioid Manufacturers. County hereby authorizes Counsel to file a lawsuit against one or all of the Opioid Manufacturers ("Lawsuit") upon the terms and conditions set forth herein.

RESPONSIBILITIES

Counsel will prosecute the Lawsuit with diligence and keep County reasonably informed of progress and developments, and respond to County's inquiries. County understands and agrees that all fees paid to Counsel shall be as set forth in this Engagement Letter. County agrees to cooperate with Counsel in the gathering of information necessary to investigate and prosecute the Lawsuit. County further understands and agrees that the law firm of von Briesen & Roper, s.c., shall not be identified on any pleading as counsel of record for County in relation to the Lawsuit, but shall be available to assist County and Counsel in relation to the Lawsuit.

The following additional terms apply to the relationship between County and Counsel:

A. Counsel shall remain sufficiently aware of the performance of one another and the performance to ascertain if each firm's handling of the Lawsuit conforms to the Rules

of Professional Conduct. Counsel shall be available to County regarding any concerns on the part of County relating to the performance of Counsel. Counsel shall at all times remain ethically and financially responsible to the County for the services of Counsel set forth herein.

B. As set forth below, County's responsibility for attorney fees and expenses is contingent upon the successful outcome of the Lawsuit, as further defined below. Counsel have agreed in writing as to the appropriate split of attorney fees and expenses. Specifically, in the event of a Recovery (as defined below), the attorney fees will be split between the law firms as follows:

Firm Name	Percentage of Fees if Successful
Local Counsel	5%
von Briesen & Roper, s.c.	10%
Crueger Dickinson LLC	42.5%
Simmons Hanly Conroy LLC	42.5%

The split of attorneys' fees between Counsel may be subject to change. In the event of such an amendment, the County will be notified in writing of that amendment.

C. Counsel and County understand and agree that Counsel will all be considered attorneys for County. As such, each and all of Counsel will adhere to the Rules of Professional Responsibility governing the relationship between attorney and client.

ACTUAL AND POTENTIAL CONFLICTS OF INTEREST AND WAIVER OF CONFLICT

As County is aware, Counsel contemplate entering into the same arrangement as that set forth in this Engagement Letter with other counties and municipalities in Wisconsin and elsewhere. Counsel believe that the goals and objectives of County are aligned with the goals and objectives of all other counties and municipalities with respect to the Lawsuit. Counsel do not believe that to achieve the goals of the Lawsuit, either County or another county or municipality must take a position that is adverse to the interests of the other. However, to the extent any issue may arise in this matter about which County disagrees with another county or municipality, and one of you may wish to pursue a course that benefits one but is detrimental to the interest of the other, we cannot advise County or assist County or any other county or municipality in pursuing such a course. That is to say, Counsel cannot advocate for County's individual interests at the expense of the other counties or municipalities that Counsel represent in a Lawsuit. Counsel do not believe that this poses a problem because County's interests are currently aligned with the other counties and municipalities that are or may be in the Lawsuit. Counsel are confident that their representation of County will not be limited in this matter by representation of any other county or municipality, but County should consider these consequences of joint representation in deciding whether to waive this conflict.

In addition to the material limitation discussed above, there are other consequences for County in agreeing to joint representation. Because each county or municipality would be a client of Counsel, Counsel owe equal duties of loyalty and communication to each client. As such, Counsel must share

all relevant information with all counties and municipalities who are clients in relation to the Lawsuit and Counsel cannot, at the request of one county or municipality, withhold relevant information from the other client. That is to say, Counsel cannot keep secrets about this matter among the counties and municipalities who are clients of Counsel with respect to the Lawsuit. Also, lawyers normally cannot be forced to divulge information about communications with their clients because it is protected by the attorney-client privilege. However, because County would be a joint client in the same matter with other counties and municipalities, it is likely that were there to be a future legal dispute between County and other counties or municipalities that engage Counsel about this matter, the attorney-client privilege would not apply, and each would not be able to invoke the privilege against the claims of the other.

Further, while County's position is in harmony with other counties and municipalities presently, and the conflict discussed above is waivable, facts and circumstances may change. For example, County may change its mind and wish to pursue a course that is adverse to the interests of another county or municipality and the conflict may become unwaivable. In that case, depending upon the circumstances, Counsel may have to withdraw from representing either County or another county or municipality and County would have to bear the expense, if County chooses, of hiring new lawyers who would have to get up to speed on the matter.

County is not required to agree to waive this conflict, and County may, after considering the risks involved in joint representation, decline to sign this Engagement Letter. By signing this Engagement Letter, County is signifying its consent to waiving the conflict of interest discussed herein.

Other than the facts and circumstances related to the joint representation of numerous counties and municipalities, Counsel are unaware of any facts or circumstances that would prohibit Counsel from providing the services set forth in this Engagement Letter. However, it is important to note that the law firm of von Briesen & Roper, s.c., is a relatively large law firm based in Wisconsin and represents many companies and individuals. It is possible that some present and future clients of von Briesen & Roper, s.c., will have business relationships and potential or actual disputes with County. von Briesen & Roper, s.c., will not knowingly represent clients in matters that are actually adverse to the interests of County without County's permission and informed consent. von Briesen & Roper, s.c, respectfully requests that County consent, on a case by case basis, to von Briesen & Roper, s.c.'s representation of other clients whose interests are, or maybe adverse to, the interests of County in circumstances where County has selected other counsel and where von Briesen & Roper, s.c., has requested a written conflict waiver from County after being advised of the circumstances of the potential or actual conflict and County has provided informed consent.

FEES FOR LEGAL SERVICES AND RESPONSIBILITY FOR EXPENSES

A. Calculation of Contingent Fee

There is no fee for the services provided herein unless a monetary recovery acceptable to County is obtained by Counsel in favor of County, whether by suit, settlement, or otherwise ("Recovery"). County understands and agrees that a Recovery may occur in any number of different fashions such as final judgment in the Lawsuit, settlement of the Lawsuit, or appropriation to County following a nationwide settlement or extinguishing of claims in lawsuits and matters similar to the Lawsuit. Counsel agree to advance all costs and expenses of Counsel, and the Lawsuit associated with investigating and prosecuting the Lawsuit provided, however, that the costs and expenses associated with County cooperating with Counsel in conjunction with the Lawsuit and otherwise performing its responsibilities under this Engagement Letter are the responsibility of County. In consideration of the legal services to be rendered by Counsel, the contingent attorneys' fees for the services set forth in this

Engagement Letter shall be a gross fee of 25% of the Recovery, which sum shall be divided among Counsel as set forth in the above chart.

Upon the application of the applicable fee percentage to the gross Recovery, and that dollar amount set aside as attorneys' fees to Counsel, the amount remaining shall first be reduced by the costs and disbursements that have been advanced by Counsel, and that amount shall be remitted to Counsel. By way of example only, if the gross amount of the Recovery is $1,000,000.00, and costs and disbursements are $100,000.00, then the fee to Counsel and shall be $250,000, the costs amount of $100,000 shall be deducted from the balance of $750,000.00, and the net balance owed to County shall be $650,000. The costs and disbursements which may be deducted from a Recovery include, but are not limited to, the following, without limitation: court fees, process server fees, transcript fees, expert witness fees and expenses, courier service fees, appellate printing fees, necessary travel expenses of attorneys to attend depositions, interview witnesses, attend meetings related to the scope of this Engagement Letter and the like, and other appropriate matter related out-of-pocket expenses. In the event that any Recovery results in a monetary payment to County that is less than the amount of the costs incurred and/or disbursements made by Counsel, County shall not be required to pay Counsel and any more than the sum of the full Recovery.

B. Nature of Contingent Fee

No monies shall be paid to Counsel for any work performed, costs incurred or disbursements made by Counsel in the event no Recovery to County has been obtained. In the event of a loss at trial due to an adverse jury verdict or a dismissal of the Lawsuit by the court, no monies shall be paid to Counsel for any work performed, costs incurred or disbursements made by Counsel. In such an event, neither party shall have any further rights against the other.

C. Disbursement of Recovery Proceeds to County

The proceeds of any Recovery on County's behalf under the terms of this Engagement Letter shall be disbursed to County as soon as reasonably practicable after receipt by Counsel. At the time of disbursement of any proceeds from a Recovery, County will be provided with a detailed disbursement sheet reflecting the method by which attorney's fees have been calculated and the expenses of litigation that are due to Counsel from such proceeds. Counsel are authorized to retain out of any moneys that may come into their hands by reason of their representation of County the fees, costs, expenses and disbursements to which they are entitled as determined in this Engagement Letter.

TERMINATION OF REPRESENTATION

This Engagement Letter shall cover the period from the date first indicated below until the termination of the legal services rendered hereunder, unless earlier terminated as provided herein. This Engagement Letter may be terminated by County at any time, and in the event of such termination, neither party shall have any further rights against the other, except that in the event of a Recovery by County against the Opioid Manufacturers subsequent to termination, Counsel shall have a statutory lien on any such recovery as provided by applicable law and further maintain rights in the nature of *quantum meruit* to recover fees, costs and expenses reasonably allocable to their work prior to termination. Counsel may withdraw as County's attorneys at any time for the following reasons:

A. If Counsel determine, in their sole discretion, that County's claim lacks merit or that it is not worthwhile to pursue the Lawsuit further; or

B. For Good Cause. For purposes of this Paragraph, Good Cause may include County's failure to honor the terms of the Engagement Letter, County's failure to follow Counsel's advice on a material matter, or any fact or circumstance that would, in the view of Counsel, impair an effective attorney-client relationship or would render continuing representation unlawful or unethical. If terminated for Good Cause, County will take all steps necessary to free Counsel of any obligation to perform further, including the execution of any documents (including forms for substitution of counsel) necessary to complete withdrawal provided, however, that Counsel shall have a statutory lien on any Recovery as provided by applicable law and further maintain rights in the nature of *quantum meruit* to recover fees, costs and expenses reasonably allocable to their work prior to termination.

SETTLEMENT

County has the authority to accept or reject any final settlement amount after receiving the advice of Counsel. County understands settlements are a "compromise" of its claim(s), and that Counsel's fee, as set forth above, applies to settlements also. For example, if a settlement is reached, and includes future or structured payments, Counsel's fee shall include its contingent portion of those future or structured payments.

NO GUARANTEE OF RECOVERY

County understands and acknowledges that dispute resolution through litigation often takes years to achieve. County understands and acknowledges that there is no guarantee or assurances of any kind regarding the likelihood of success of the Lawsuit, but that Counsel will use their skill, diligence, and experience to diligently pursue the Lawsuit.

LIMITED LIABILITY

von Briesen & Roper, s.c., and Crueger Dickinson LLC are limited liability entities under Wisconsin law. This means that if Counsel fails to perform duties in the representation of County and that failure causes County damages, the firms comprising Counsel and the shareholder(s) or principals directly involved in the representation may be responsible to County for those damages, but the firm's other shareholders or principals will not be personally responsible. Counsel's professional liability insurance exceeds the minimum amounts required by the Wisconsin Supreme Court for limited liability entities of similar size.

COMMUNICATION BY E-MAIL

Counsel primarily communicates with its clients via unencrypted internet e-mail, and this will be the way in which communications occur with County. While unencrypted e-mail is convenient and fast, there is risk of interception, not only within internal networks and the systems used by internet service providers, but elsewhere on the internet and in the systems of our clients and their internet service providers.

FILE RETENTION AND DESTRUCTION

In accordance with Counsel's records retention policy, most paper and electronic records maintained are subject to a 10-year retention period from the last matter activity date or whatever date deemed appropriate. Extended retention periods may apply to certain types of matters or pursuant to County's specific directives.

After the expiration of the applicable retention period, Counsel will destroy records without further notice to County, unless County otherwise notifies in writing.

MISCELLANEOUS

This Engagement Letter shall be governed by and construed in accordance with the laws of the State of Wisconsin, without regard to conflicts of law rules. In the event of any dispute arising out of the terms of this Engagement Letter, venue for any such dispute shall be exclusively designated in the State of Wisconsin Circuit Court for Milwaukee County, Wisconsin, or in the United States District Court for the Eastern District of Wisconsin.

It is expressly agreed that this Engagement Letter represents the entire agreement of the parties, that all previous understandings are merged in this Engagement Letter, and that no modification of this Engagement Letter shall be valid unless written and executed by all parties.

It is expressly agreed that if any term or provision of this Engagement Letter, or the application thereof to any person or circumstance, shall be held invalid or unenforceable to any extent, the remainder of this Engagement Letter, or the application of such term or provision to persons or circumstances other than those to which it is held invalid or unenforceable, shall not be affected thereby; and every other term and provision of this Engagement Letter shall be valid and shall be enforced to the fullest extent permitted by law.

The parties acknowledge that they have carefully read and fully understand all of the provisions of this Engagement Letter, and that they have the capacity to enter into this Engagement Letter. Each party and the person signing on behalf of each party, represents that the person signing this Engagement Letter has the authority to execute this document and thereby bind the party hereto on whose behalf the person is signing. Specifically, County acknowledges that it is bound by this Engagement Letter, has satisfied all conditions precedent to execution of this Engagement Letter and will execute all the necessary documents that may be required by its governing statutes and/or code.

CONCLUSION

Counsel are pleased to have this opportunity to be of service to County. If at any time during the course of representation you have any questions or comments about our services or any aspect of how we provide services, please don't hesitate to call one or all of the individuals listed below.

Very truly yours,

CRUEGER DICKINSON LLC

Erin K. Dickinson

SIMMONS HANLY CONROY LLC

Paul J. Hanly

von BRIESEN & ROPER, s.c.

Andrew T. Phillips

[NAME OF COUNTY] agrees to retain the services of Counsel all upon the terms and conditions specified above.

By:

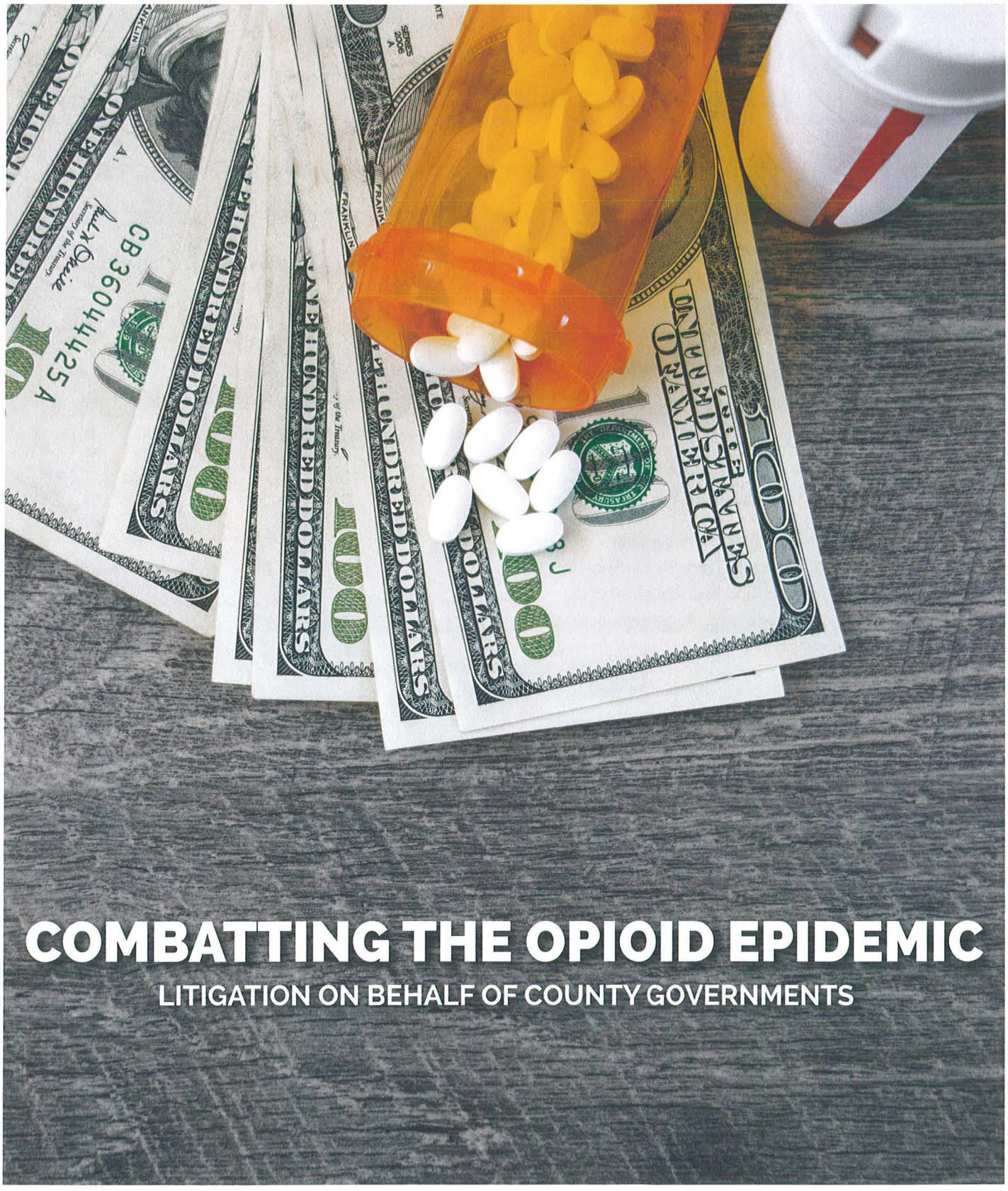
Title:

Date:

Crueger Dickinson

SIMMONS HANLY CONROY
A NATIONAL LAW FIRM

von Briesen
von Briesen & Roper, s.c. | Attorneys at Law



COMBATTING THE OPIOID EPIDEMIC

LITIGATION ON BEHALF OF COUNTY GOVERNMENTS

Crueger Dickinson | SIMMONS HANLY CONROY A NATIONAL LAW FIRM | von Briesen von Briesen & Roper, s.c. | Attorneys at Law

THE OPIOID EPIDEMIC: A PUBLIC HEALTH CRISIS

Opioid addiction and abuse have reached epidemic levels over the past decade. Indeed, on March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."[1]

In the last decade, the epidemic has exploded. From 1999 to 2013 the amount of opioids dispensed in the United States quadrupled.

In 2013, nearly 207 million opioid prescriptions were written. A year later, that number grew to 259 million.

Those sales are big business for the pharmaceutical companies that manufacture and sell opioids including Purdue, Teva, Janssen, Cephalon and Endo (referred to as "Pharma"). In 2015 alone, the sale of opioids generated nearly $10 Billion in revenue for Pharma.

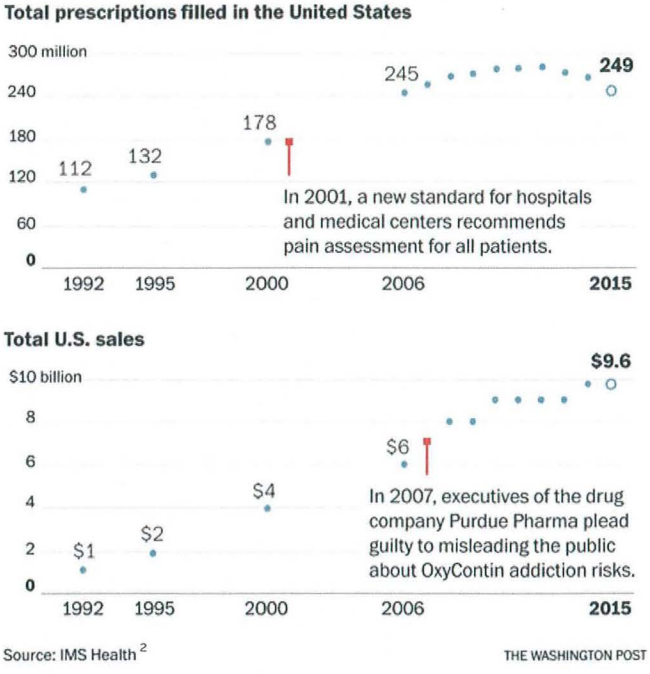
Sales and profits have grown dramatically over the past several decades.

4X

From 1999 to 2013, the amount of prescription opioids dispensed in the U.S. nearly **quadrupled.**

Tracking opioid use and sales

The opioid-drug market has grown dramatically over the past 25 years.



Source: IMS Health [2]

THE WASHINGTON POST

1 http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm

2 https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.2d1327bf59ae

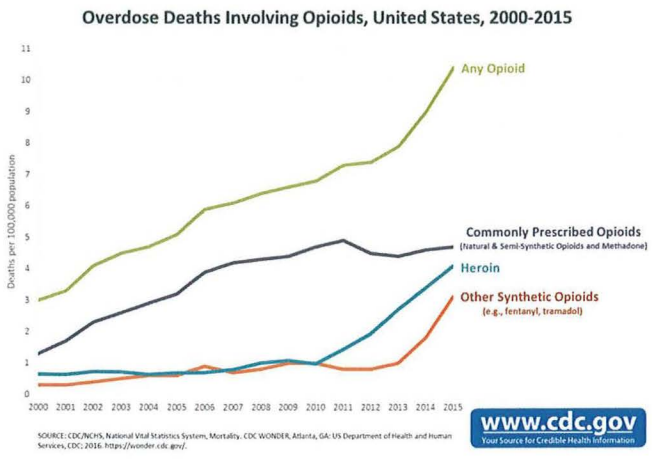
This spike in sales has had devastating and catastrophic effects. 2015 Data from the National Survey on Drug Use and Health showed that in the year 2013 over a third of the people in the United States had used prescription opioids with a significant number suffering from addiction as a result.

37.8% Americans used prescription opioids
(91.8 MILLION PEOPLE)

4.7% misused them
(11.5 MILLION PEOPLE)

.8% had a use disorder
(1.9 MILLION PEOPLE)

Additionally, deaths from opioids dramatically spiked with increased sales:



As described below, these dramatically increased sales and the spike in abuse and resultant deaths directly corresponds to Pharma's decision to market opioids for long-term use despite their known addictive effects.

PHARMA'S ROLE IN CREATING THE OPIOID EPIDEMIC

Opioids were historically used to provide effective treatment for short-term pain management. Controlled studies of the safety and efficacy of opioids were limited to short-term use. Pharma knew the limitations of the controlled studies. However, Pharma knew that profits could sky rocket if they were able to market and sell opioids for long-term use, including to treat chronic pain. In order to expand their market and achieve a dramatic increase in profits, Pharma decided to create a false marketing campaign designed to give the medical community and the public the false impression that opioids were safe and efficacious for long-term use. This false marketing campaign began in the late 90s, but exponentially increased starting in about 2006 and continues to the present.

Pharma was successful.

SINCE 1999
Prescription sales of opioids have **quadrupled**

IN 2010
254 million opioid prescriptions were written

IN 2013
37.4% of the population had been prescribed Opioids

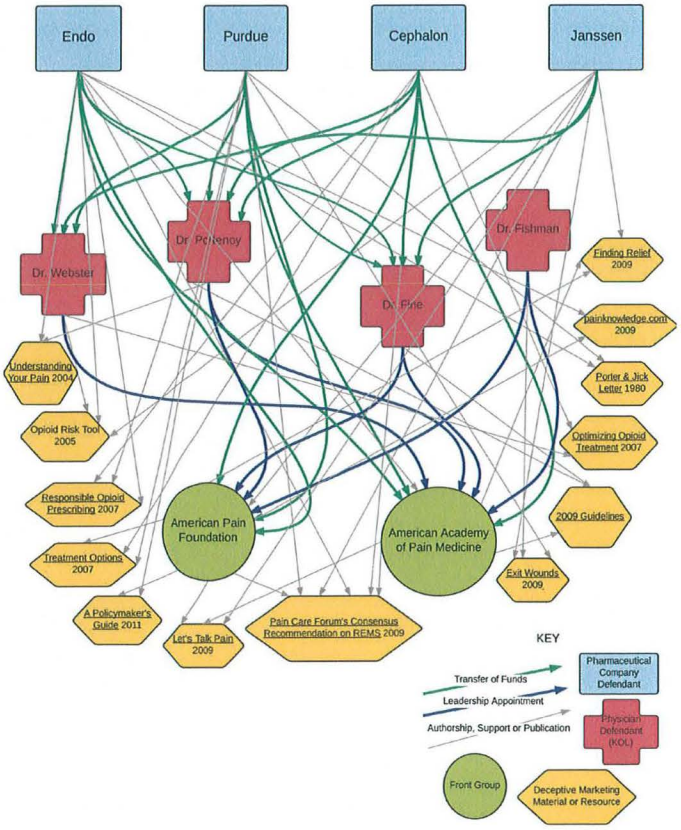
The result was a public health crisis that has had a profound impact on individuals, families and communities across the country.

The National Institute for Health ("NIH") identified Pharma as directly responsible for this crisis. In 2015, the NIH found that "several factors are likely to have contributed to 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.*"[3]

That "aggressive marketing campaign" included distorting medical and public perception of existing scientific data to create the false impression that opioids were safe and efficacious for long-term use. To accomplish this, Pharma poured money into generating articles, continuing education courses, sales groups and advocacy groups to create a phony "consensus" supporting the long-term use of opioids. Pharma and a select group of doctors and "front groups" banded together to create false legitimacy and the impression that these drugs were safe and efficacious for long-term use.

91 Americans die every day from an **opioid overdose** (that includes prescription opioids and heroin).

The following graphic depicts how this worked:



County of Suffolk v. Purdue Pharm L.P. et al., Case No. NYSCEF 613760/2016, Doc. No. 2, Ex. A.

WHY DID PHARMA DO THIS?

The answer is simple. Pharma made blockbuster profits. In 2012 alone, Pharma raked in $8 Billion from the sale of opioids. Purdue alone made $3.1 Billion from the sale of the opioid Oxycontin.

3 https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse

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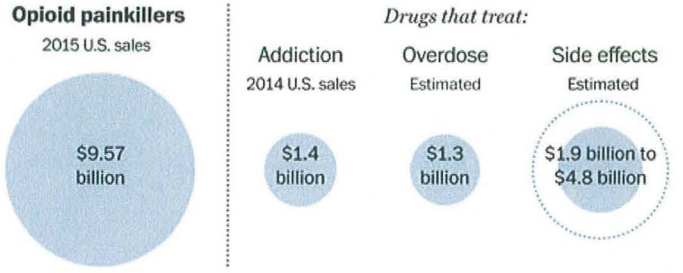
Not only has the Pharma industry profited from selling opioids but companies have also profited from treating the effects. As illustrated in a recent Washington Post article, the profits have been enormous:

Drugs to treat the effects of drugs

The nearly $9.6 billion industry around opioid pain management has begotten a number of new billion-dollar markets for addiction, overdose and side effects such as constipation.



Sources: IMS Health, Credence Research, Transparency Market Research, One Equity Research [4]

THE WASHINGTON POST

COUNTIES BEAR THE COSTS

While Pharma was raking in profits, county governments have been forced to spend a significant amount of money combatting this epidemic. Costs to counties include health care costs, addiction and treatment costs, social costs, programming, training and education costs, criminal justice and victimization costs and lost productivity.

COUNTIES AND STATES FILE LAWSUITS

A number of government entities have brought litigation against the Pharma companies for their role in creating the Opioid Epidemic. This includes the State of Kentucky, the State of Ohio, the City of Chicago and counties in New York, West Virginia and Illinois. More and more cases are filed every week. A chart summarizing the current litigation is attached in the Appendix hereto (Tab 1). Additionally, major news outlets have been covering the opioid epidemic and resulting litigation. (Several recent examples have been included in the attached Appendix, Tab 2).

HOLDING PHARMA ACCOUNTABLE: CLAIMS

Lawsuits seek to hold opioid manufacturers accountable for the costs communities incur as a result of the opioid epidemic.

Lawsuits have alleged that Pharma and a select group of doctors worked together to create a false impression of the safety and efficacy of opioids for long term use. Allegations are that Pharma and the doctors misled the medical community and consumers into believing that opioids were non-addictive and were a viable option for treatment of chronic pain. Legal claims have included:

- Misrepresentation
- Consumer Fraud/Violation of Consumer Protection Statutes
- False Advertising
- Nuisance
- Civil RICO

Different cases have taken different approaches, but the facts and allegations are similar. A sample of one of the Complaints, filed by Suffolk County, New York is included in the attached Appendix (Tab 3).

4 https://www.washingtonpost.com/national/the-drug-industrys-answer-to-opioid-addiction-more-pills/2016/10/15/181a529c-8ae4-11e6-bff0-d53f592f176e_story.html?utm_term=.2d1327bf59ae

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WHAT ARE THE DOLLAR FIGURES?

While it is still early in the investigation into the exact costs to counties, states and municipalities, costs of the Opioid Epidemic are staggering. Indeed, in 2016 researchers from the CDC estimated the annual economic burden of prescription opioid abuse in the U.S. at $78.4 Billion. The study further broke down this cost as follows:

LOST PRODUCTIVITY
$42 Billion (53.3%)

HEALTH INSURANCE
$26.1 Billion (33.3%)

CRIMINAL JUSTICE
$7.6 Billion (9.7%)

SUBSTANCE ABUSE TREATMENT
$2.8 Billion (3.6%)

[5]

While the CDC study did not attempt to estimate damages to county governments, the economic impact is significant and, to date, unreimbursed by Pharma.

5 Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, October 2016, 54(10): 901 – 906.

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FREQUENTLY ASKED QUESTIONS

WHAT IS THE OPIOID LITIGATION AND WHY DOES IT AFFECT COUNTIES?

State and local governments around the country have begun to file lawsuits against several major manufacturers (Purdue, Janssen, Endo, Cephalon and others)(referred to as "Pharma") for their role in creating the Opioid Epidemic. These manufacturers flooded the market with highly addictive drugs, claiming they were safe and efficacious for long term use, manufactured studies to support these false claims and knowingly misrepresented the addictive nature of these drugs. As a result of these misrepresentations, millions of Americans lives have been impacted or destroyed (commonly referred to as the "Opioid Epidemic"). The Opioid Epidemic has in turn imposed huge costs on both county and state governments around the country including health care costs, substance abuse, treatment and prevention costs, criminal justice costs and productivity costs.

LOST PRODUCTIVITY
$42 Billion (53.3%)

HEALTH INSURANCE
$26.1 Billion (33.3%)

CRIMINAL JUSTICE
$7.6 Billion (9.7%)

SUBSTANCE ABUSE TREATMENT
$2.8 Billion (3.6%)

6

WHAT IS THE ECONOMIC IMPACT OF THE OPIOID EPIDEMIC?

While it is still early in the investigation, studies have analyzed the economic impact of the Opioid Epidemic. In the most recent major study, published in 2016 by CDC researchers, the annual estimated economic burden of prescription opioid abuse in the United States was determined to be $78.4 Billion. Of that number the economic impact broke down as follows:

Predictably, as the epidemic has worsened, so has the economic burden. Indeed, a similar study in 2007 found the annual economic impact was $55.7 Billion. And a recent 2017 study funded by the U.S. Department of Health and Human Services found that more than one third of U.S. civilian, noninstitutionalized adults reported prescription opioid use, with substantial numbers reporting misuse and use disorders. As the problem has worsened since 2013, it is expected that the impact has correspondingly worsened.

6 Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, October 2016, 54(10): 901 – 906.

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WHAT IS THE GOAL OF THE OPIOID LITIGATION?

To hold Pharma responsible for their role in creating the Opioid Epidemic and to return to the counties the money spent battling the epidemic and the expense of other critical programming. While it is unrealistic to think that the lawsuit will solve the problem, Pharma should be responsible for funding solutions to a problem they created.

WHAT KINDS OF COSTS WOULD A LAWSUIT SEEK TO RECOVER?

The counties would seek repayment for the costs they have expended related to the Opioid Epidemic. Those costs include but are not limited to:

- County funded healthcare costs for employees and dependents related to opioid addiction, substance abuse treatment, hospitalizations, etc.
- County funded programs for residents for prevention, treatment, health visits, substance abuse programs etc.
- Criminal Justice and law enforcement costs associated with opioids
- Loss of county employee productivity related to opioid abuse and addiction
- General societal mayhem and opioid related death costs

WHAT IS THE REASON THE COUNTIES SHOULD GET INVOLVED IN THE OPIOID LITIGATION?

The only way to recover any of the significant costs the counties have faced as a result of Pharma's role in the Opioid Epidemic is to bring suit. Any county that does not get involved risks receiving no recovery. While recovery in this type of litigation is not certain, one certain way to get nothing is to stay out of the litigation.

WHAT IF THE COUNTIES DO NOT GET INVOLVED?

Counties who do not get involved will not get a recovery in the event that there is one.

WHO WILL PAY FOR THE LITIGATION?

The counties will not be asked to bear the costs of the Opioid Litigation. The law firms proposing to represent the counties will work on a contingent fee basis (only getting paid out of a portion of the recovery if there is one) and bearing all costs of the litigation.

WHAT WILL BE EXPECTED OF A COUNTY BRINGING SUIT?

Counties bringing suit will be expected to participate in some significant ways, the most major of which is document collecting and information gathering to support the county's claim for costs associated with the Opioid Epidemic. The team of private attorneys will work on site with county employees to help identify, gather and assemble this information; however, county employee time will also be necessary. Affected departments will likely be Health and Human Services, Human Resources, Medical Examiner/Coroner, District Attorney's Office, Office of the Sheriff, Circuit Courts, Department of Administration.

WHAT IS THE REASON TO COORDINATE EFFORTS ACROSS COUNTIES IN THE LITIGATION?

It will be very important to coordinate efforts both among counties in each state and between counties nationally. Government entities will face a well-financed, well-funded and coordinated defense from Pharma. Unless a critical mass of counties not only file suit and coordinate efforts, it is a safe bet that Pharma will simply continue to fight each individual case without contemplating a resolution.

WILL THE STATE BE INVOLVED AND HOW WILL THAT IMPACT THE COUNTIES AND THEIR ABILITY TO RECOVER?

The State of Ohio has brought suit and other states are contemplating suit. It is safe to assume that state governments will bring similar suits. The states and counties will have separate damages, however, and the counties should be able to recover even if the states bring suit. As the tobacco litigation demonstrated, there is no reason to expect that the counties can simply let the states file suit and wait for their portion of the states' recovery. The best way for the counties to protect their interests is to pursue their own litigation.

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Simmons Hanly Conroy LLC
phanly@simmonsfirm.com
212 784 6401

ANDREW T. PHILLIPS
von Briesen & Roper
aphillips@vonbriesen.com
414 287 1570

RESOLUTION NO. _____

TO THE HONORABLE BOARD OF SUPERVISORS OF _____ COUNTY,

_____

MEMBERS,

WHEREAS, _____ County ("County") is concerned with the recent rapid rise in troubles among County citizens, residents, and visitors in relation to problems arising out of the use, abuse and overuse of opioid medications, which according to certain studies, impacts millions of people across the country; and

WHEREAS, issues and concerns surrounding opioid use, abuse and overuse by citizens, residents and visitors are not unique to County and are, in fact, issues and concerns shared by all other counties in _____ and, for that matter, states and counties across the country, as has been well documented through various reports and publications, and is commonly referred to as the Opioid Epidemic ("Opioid Epidemic:); and

WHEREAS, the societal costs associated with the Opioid Epidemic are staggering and, according to the Centers for Disease Control and Prevention, amount to over $75 billion annually; and

WHEREAS, the National Institute for Health has identified the manufacturers of certain of the opioid medications as being directly responsible for the rapid rise of the Opioid Epidemic by virtue of their aggressive and, according to some, unlawful and unethical marketing practices; and

WHEREAS, certain of the opioid manufacturers have faced civil and criminal liability for their actions that relate directly to the rise of the Opioid Epidemic; and

WHEREAS, County has spent millions in unexpected and unbudgeted time and resources in its programs and services related to the Opioid Epidemic; and

WHEREAS, County is responsible for a multitude of programs and services, all of which require County to expend resources generated through state and federal aid, property tax levy, fees and other permissible revenue sources; and

WHEREAS, County's provision of programs and services becomes more and more difficult every year because the costs associated with providing the Opioid Epidemic programs and services continue to rise, yet County's ability to generate revenue is limited by strict levy limit caps and stagnant or declining state and federal aid to County; and

WHEREAS, all sums that County expends in addressing, combatting and otherwise dealing with the Opioid Epidemic are sums that cannot be used for other critical programs and services that County provides to County citizens, residents and visitors; and

WHEREAS, County has been informed that numerous counties and states across the country have filed or intend to file lawsuits against certain of the opioid manufacturers in an effort to force the persons and entities responsible for the Opioid Epidemic to assume financial responsibility for the costs associated with addressing, combatting and otherwise dealing with the Opioid Epidemic; and

WHEREAS, County has engaged in discussions with representatives of the law firms of Crueger Dickinson LLC, Simmons Hanly Conroy LLC von Briesen & Roper, s.c., (the "Law Firms") related to the potential for County to pursue certain legal claims against certain opioid manufacturers; and

WHEREAS, County has been informed that the Law Firms have the requisite skill, experience and wherewithal to prosecute legal claims against certain of the opioid manufacturers on behalf of public entities seeking to hold them responsible for the Opioid Epidemic; and

WHEREAS, the Law Firms have proposed that County engage the Law Firms to prosecute the aforementioned claims on a contingent fee basis whereby the Law Firms would not be compensated unless County receives a financial benefit as a result of the proposed claims and the Law Firms would advance all claim-related costs and expenses associated with the claims; and

WHEREAS, all of the costs and expenses associated with the claims against certain of the opioid manufacturers would be borne by the Law Firms; and

WHEREAS, the Law Firms have prepared an engagement letter, which is submitted as part of this Resolution ("Engagement Letter") specifying the terms and conditions under which the Law Firms would provide legal services to County and otherwise consistent with the terms of this Resolution; and

WHEREAS, County is informed that the _____Counties Association has engaged in extensive discussions with the Law Firms and has expressed a desire to assist the Law Firms, County and other counties in the prosecution of claims against certain of the opioid manufacturers; and

WHEREAS, County would participate in the prosecution of the claim(s) contemplated in this Resolution and the Engagement Letter by providing information and materials to the Law Firms and, as appropriate, the Wisconsin Counties Association as needed; and

WHEREAS, County believes it to be in the best interest of County, its citizens, residents, visitors and taxpayers to join with other counties in and outside Wisconsin in pursuit of claims against certain of the opioid manufacturers, all upon the terms and conditions set forth in the Engagement Letter; and

WHEREAS, by pursuing the claims against certain of the opioid manufacturers, County is attempting to hold those persons and entities that had a significant role in the creation of the Opioid Epidemic responsible for the financial costs assumed by County and other public agencies across the country in dealing with the Opioid Epidemic.

NOW, THEREFORE, BE IT RESOLVED:

County authorizes, and agrees to be bound by, the Engagement Letter and hereby directs the appropriate officer of the County to execute the Engagement Letter on behalf of the County; and

BE IT FURTHER RESOLVED:

County shall endeavor to faithfully perform all actions required of County in relation to the claims contemplated herein and in the Engagement Letter and hereby directs all County personnel to cooperate with and assist the Law Firms in relation thereto.

The County Clerk shall forward a copy of this Resolution, together with the signed Engagement Letter, to the _____Counties Association, _____(ADDRESS)

Respectfully submitted this _____ day of _____, 2017.

[COMMITTEE]

**[FISCAL NOTE]

29264534_1.DOCX

BBB Accredited

The firm has been a BBB accredited business since 2003 and has maintained an A+ rating during that time. The BBB has processed 0 total complaints about this company in the last 36 months, the BBB's standard reporting period.

U.S. News & World Report/ Best Law Firm

Since 2014, the firm has been ranked one of the 'Best Law Firms' in the country by U.S. News & World Report and Best Lawyers. The annual ranking is based on a rigorous research process including client and lawyer evaluations, peer reviews from leading attorneys and a law firm survey completed by the firm.

Super Lawyers & Rising Stars

Firm attorneys have been represented on the Super Lawyers and Rising Stars lists, ranking consecutively since 2006. Super Lawyers recognizes outstanding lawyers who have attained a high degree of peer recognition and professional achievement. The annual selections are made using a rigorous, multi-phased process of statewide lawyer surveys, an independent research evaluation of candidates and peer reviews by practice area.

Simmons Hanly Conroy LLC

Martindale-Hubbell AV rating

Attorneys at Simmons Hanly Conroy have earned AV Preeminent ratings from Martindale-Hubbell. An AV rating, which identifies a lawyer with a very high to preeminent legal ability, is a prestigious peer-reviewed analysis of the attorney's expertise, experience, integrity and overall professional excellence.

THE NATIONAL LAW JOURNAL 2016

ELITE TRIAL LAWYERS

Named Among America's Elite Trial Lawyers | Products Liability

The National Law Journal, the nation's top legal publication, and Law.com teamed to select law firms doing the most creative and substantial work on the plaintiff's side. This is the third year Simmons Hanly Conroy has been included among the nation's top 50 firms that accomplished the largest awards for their clients in that calendar year. This year, the firm was a finalist in the Medical Devices Category.

Million & Multi-Million Dollar Advocates Forum

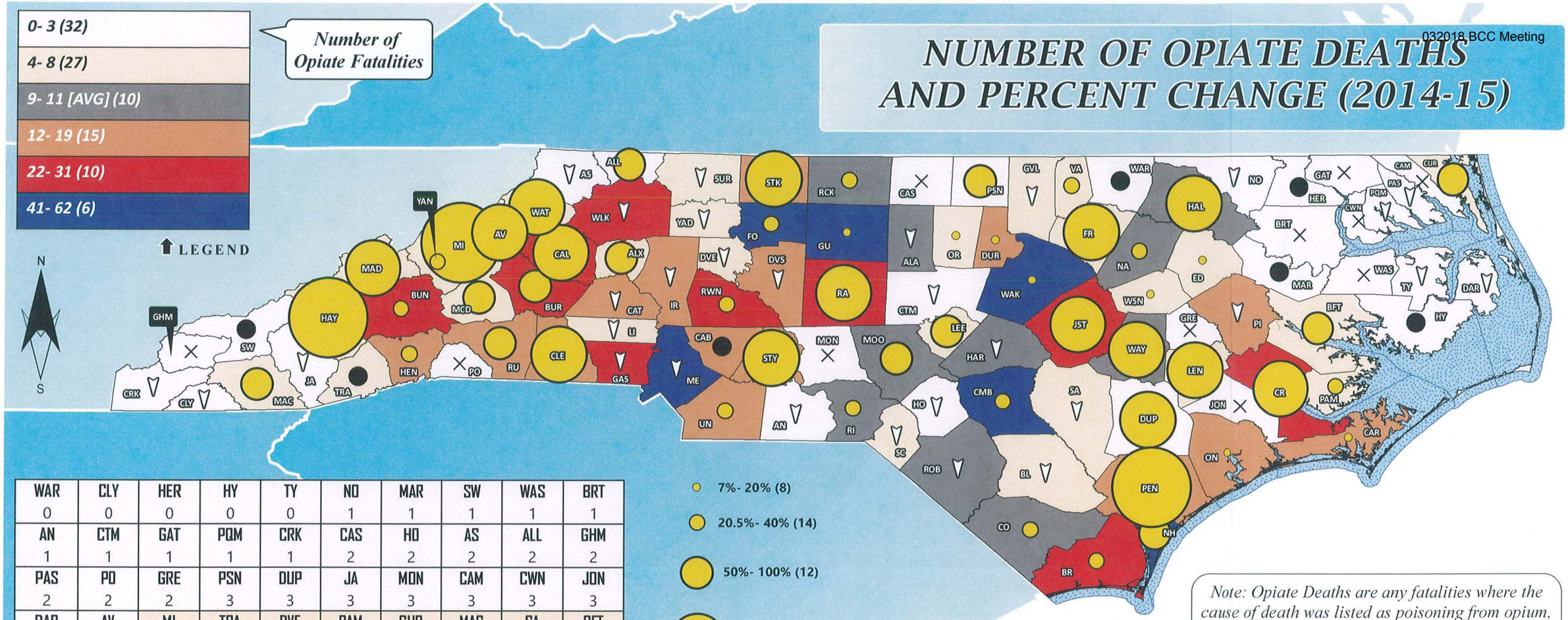
Established in 1993, the Multi-Million Dollar Advocates Forum is one of the most prestigious groups of trial lawyers in the United States. Membership is limited to attorneys who have won million and multi-million dollar verdicts and settlements. Fewer than 1 percent of U.S. lawyers are members.

SIMMONS HANLY CONROY

A NATIONAL LAW FIRM

We stand for our clients.

NUMBER OF OPIATE DEATHS AND PERCENT CHANGE (2014-15)



WAR 0	CLY 0	HER 0	HY 0	TY 0	NO 1	MAR 1	SW 1	WAS 1	BRT 1
AN 1	CTM 1	GAT 1	PQM 1	CRK 1	CAS 2	HO 2	AS 2	ALL 2	GHM 2
PAS 2	PO 2	GRE 2	PSN 3	DUP 3	JA 3	MON 3	CAM 3	CWN 3	JON 3
DAR 3	AV 3	MI 4	TRA 4	DVE 4	PAM 4	CUR 4	MAC 4	SA 5	BFT 5
VA 5	SC 5	GVL 5	BL 5	YAD 5	LI 5	YAN 5	WSN 6	ED 6	MAD 6
ALX 6	OR 6	LEN 7	FR 7	LEE 7	SUR 7	WAT 7	MCD 8	HAY 8	CO 9
WAY 9	HAL 10	HAR 10	RCK 11	ALA 11	NA 11	RI 11	ROB 11	MOO 11	PI 12
STY 12	STK 13	HEN 13	RU 14	PEN 14	IR 15	CAR 15	ON 15	DUR 17	CAB 17
CAT 17	CLE 18	UN 18	DVS 19	CR 22	JST 23	CAL 23	BR 24	WLK 24	RWN 29
BUN 29	GAS 30	RA 30	BUR 31	CMB 41	NH 45	GU 47	FO 53	ME 61	WAK 62

Source: NC Deparment of Health and Human Services, Injury and Violence Prevention Branch

Note: Opiate Deaths are any fatalities where the cause of death was listed as poisoning from opium, heroin, other opioids, methadone and/or other synthetic opioid. This map allows us to analyze two variables: (1) raw count of opiate deaths in the year 2015 per county, which are represented by the legend in the upper left hand corner and by the figures in the table on the left, and (2) percent change/increase from the number of opiate deaths in 2014, which is represented by the symbols next to the table. In regards to North Carolina's opiate crisis, this allows us to see which counties are in need of more help and which counties are succeeding in their efforts to reduce the number of fatal opiate cases. All counties marked as "percent change NA" are counties that did not report any opiate fatalities in 2014.

Forum on Opioid-Related Legal Matters

Agenda

9:00 – 9:15	**NCACC Introductory Remarks**
9:15 – 11:00	**Law Firm Presentations** 9:15 – 10:00 • Paul Ferrell, Greene Ketchum Farrell Bailey & Tweel • Mike Fuller, McHugh Fuller Law Group 10:15 – 11:00 • Erin Dickinson, Crueger Dickinson Paul Hanly, Simmons Hanly Conroy
11:15 – 12:00	**Office of the N.C. Attorney General Presentation** • Swain Wood, General Counsel, Office of the Attorney General
12:00 – 12:45	**Lunch and General Q & A**
12:45 – 3:00	**County Attorneys Working Group Discussion**

Forum on Opioid-Related Legal Matters

Notes

Forum on Opioid-Related Legal Matters

Potential Questions to Consider

What is the likelihood of success?

What are the advantages and disadvantages of signing up with outside counsel?

How much work will the county need to contribute to the process?

What are the costs to the county if litigation is unsuccessful?

What type of litigation should be pursued? State? Federal?

What are the possible causes of action?

Are there statutes of limitations concerns? Issues of causation?

How does participation in the Multidistrict Litigation impact a county's potential role/recovery with any action the state takes?

How specific should damages be defined to gather county-level data?

Are there ways to label and track opioid costs?

At what level of specificity does your county track this type of data?

If not specific figures, is there a legitimate way to estimate/extrapolate costs?

List additional questions below:

Forum on Opioid-Related Legal Matters

Calculating Damages

Public Health
Cost of overdose medications (e.g., Naloxone)
Drug screening tests
Cost of treating uninsured patients for opiate-related dependence
Treatment costs for babies born with positive toxicology
Substance abuse treatment costs

Social Services
Number of foster care placements attributable to opiate-related causes
Increased number of staff/hours to cover opiate-related cases

Law Enforcement
Cost of additional sheriff department hours attributable to opiate-related response
Cost of detox treatment in detention center
Increase in jail costs attributable to opiate-related causes

Emergency Response
Increase in volume for emergency calls and responses
Coroner/medical examiner costs

Courts
Increase in caseload volume attributable to opiate-related cases

Education
Increase in Number of School Resource Officers

Capital
Cost of building and maintaining treatment facilities

List other damages below:

AGENDA ITEM 6:

PARKS AND RECREATION MATTERS

A. Vehicle Bid Award Request

MANAGER'S COMMENTS:

County staff solicited vehicle bids for one (1) new 2018 Ford F150 pickup truck. Three (3) bids were received with Asheville Ford Lincoln being the lowest responsible bidder in the amount of $22,099.97.

Board action is required to award the bid to Asheville Ford Lincoln for one (1) new 2018 Ford F150 pickup truck in the amount of $22,099.97 which includes taxes and tags.

Watauga County Parks & Recreation
231 Complex Dr. • Boone, NC 28607
(828) 264-9511
(828) 264-9523 Fax
www.wataugacounty.org

TO: Deron Geouque, County Manager

FROM: Stephen Poulos, Watauga County Parks & Recreation Director

SUBJECT: 2018 Ford F150 Truck

DATE: March 13, 2018

In our effort to update the department's truck, I have requested bids from area Ford dealerships for a 2018 Ford F150 Pickup Truck, regular cab 4x2, V6 engine, automatic transmission, air conditioning, power group, vinyl interior and white in color.

I'd like to request that this be added to the March 20th agenda for the Commissioners' Board Meeting for their consideration.

BID SUMMARY

Ashe County Ford of West Jefferson:	$22,884.36
Duncan Ford of Blacksburg:	$22,831.83
Asheville Ford Lincoln:	$22,099.97

RECOMMENDATION

Staff recommends that the County award the bid to the low bidder, Asheville Ford in Asheville, NC.

WATAUGA COUNTY
PARKS & RECREATION
231 Complex Drive • Boone, NC 28607
Phone : (828) 264-9511
Fax : (828) 264-9523
www.wataugacounty.org

Request for Quotation

Vendor: Asheville Ford Lincoln
Address: 611 Brevard Rd.
Asheville NC 28806
Phone: 828-253-2731
Fax: 828-258-6204

VENDOR READ CAREFULLY

1. This inquiry implies no obligation on the part of Watauga County.
2. Changes or suggestions offering cost economy are solicited.
3. If your product deviates from our specifications, please call our attention to the exceptions when quoting or submit samples
4. Quotations must state terms of payment and delivery time.
5. Please show address changes, if any.
6. Show discount only if NOT included in unit price.
7. Unless stated in writing below, freight costs to be paid by vendor.

This quote is due in our office by: March 13,2018

Quotation may not be considered if the information requested below is not completed, signed, and returned by the due date.

Quantity	Item	Specifications	Delivery & Freight	Terms	Unit Price	Total
1	2018 Ford F150	4x2 Regular Cab, 6.5" Box	N/A	NeT 30	20,073.36	$20,073.36
	STANDARD	122" Wheelbase	N/A	NeT30	0	
	A	Vinyl Interior	N/A	NeT30	0	
	85A	Power Equipment Group	N/A	NeT30	$911.80	$911.80
	STANDARD	17" Steel Wheels	N/A	NeT30	0	
	STANDARD	3.3 Liter, V6 Engine	N/A	NeT30	0	
	96W	Spray In Bed Liner	N/A	NeT30	$465.30	$465.30

Subtotal	$21,450.46
Shipping	0
Miscellaneous	0
Total Quote Amount	$21,450.46

If you have any questions, please contact Sharon Greer at (828) 264-9511 or sharon.greer@watgov.org

Quotation valid for: 180 days.

Quotation prepared by: Jeff Williams — Print Name and Official Title

Signature

03/05/2018 — Date

This is a quotation on the goods named, subject to the conditions note below:

Describe any conditions pertaining to these prices and any additional terms of the agreement. You may want to include contingencies that will affect the quotation.

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AGENDA ITEM 6:

PARKS AND RECREATION MATTERS

B. Out-of-State Travel

MANAGER'S COMMENTS:

Mr. Stephen Poulos, Parks and Recreation Director, and Ms. Keron Poteat, Recreation Specialist II, are requesting Board authorization to travel to Abingdon, VA. The purpose of the trip is to serve the older adult population in providing transportation and assistance for a play and lunch.

Board action is required to authorize the out-of-state travel.

WATAUGA COUNTY
PARKS & RECREATION

231 Complex Drive • Boone, NC 28607
Phone : (828) 264-9511
Fax : (828) 264-9523

www.wataugacounty.org

Memo

To: Deron, County Manager

Anita Fogle, Administrative Assistant

From: Stephen J. Poulos, Director Watauga County Parks and Recreation

Date: 3/13/2018

Re: Barter Theater Trip

Watauga County Parks and Recreation is seeking approval for a Watauga County Parks and Recreation Trip to the Barter Theater in Abingdon, Va to watch “A Facility for Living” on Thursday, March 22nd. Stephen Poulos and Keron Poteat will be driving the vans and supervising the trip.

Thanks for consideration of this request.

Day Trippin'

with Watauga County Parks & Recreation

March 22	Barter Theater Trip to see *"A Facility for Living"*
$25	Abingdon, Virginia
	Lunch at the Peppermill on your own.
	Leave @ 10 a.m. Return @ 5:30 p.m.
April 18th	Baseball & Bowling! Hickory Crawdads & Bo's
$5	Hickory & Lenoir, North Carolina
	Includes lunch at the ballpark. Snacks on your own.
	Leave @ 9 a.m. Return @ 6 p.m.
May 9th	A Walk in the Park @ Daniel Stowe Botanical Gardens
$10	Charlotte, North Carolina
	Includes admission & a box lunch.
	Leave @ 9 a.m. Return at 5:30 p.m.
May 25th	Spring Craft Fair & Piedmont Triad Farmer's Market
$5	Greensboro, North Carolina
	Includes lunch (set menu) at the Moose Café
	Leave @ 9 a.m. Return at 6 p.m.

These trips are made possible through funding from the Adult Services Coalition & the High Country Senior Games.

Watauga County Parks & Recreation
231 Complex Drive, Boone, NC
828.264.9511

paul.krause@watgov.org keron.poteat@watgov.org

Day Trippin' Registration

_____	3/22	Barter Theater	$25
_____	4/18	Hickory Crawdads & Bo's in Lenoir	$5
_____	5/9	Daniel Stowe Botanical Gardens	$10
_____	5/25	Craft Fair & Farmer's Market	$5

Office Use Only
Amount Paid _____
Date _____
Staff _____
Receipt No. _____

Participant Name _____ Gender _____ Age _____

Mailing Address _____ City _____ Zip _____

Date of Birth _____/_____/_____

Primary Phone # _____ Secondary Phone # _____

Email _____

Would you like to donate $1 (or more) to the Watauga County Parks & Recreation Scholarship Fund? This fund helps others in our community by allowing the recreation department to offer a reduction in fees or scholarships for many of our programs.

Yes _____No _____ Amount $ _____

Save the Dates!

March 22	Barter Theater Trip to see *"A Facility for Living"*
$25	Lunch at the Peppermill on your own.
	Leave @ 10 a.m. Return @ 5:30 p.m.
April 18th	Baseball & Bowling! Hickory Crawdads & Bo's
$5	Includes lunch at the ballpark. Snacks on your own.
	Leave @ 9 a.m. Return @ 6 p.m.
May 9th	A Walk in the Park @ Daniel Stowe Botanical Gardens
$10	Includes admission & a box lunch.
	Leave @ 9 a.m. Return at 5:30 p.m.
May 25th	Spring Craft Fair & Piedmont Triad Farmer's Market
$5	Includes lunch (set menu) at the Moose Café
	Leave @ 9 a.m. Return at 6 p.m.

AGENDA ITEM 7:

TAX MATTERS

A. Monthly Collections Report

MANAGER'S COMMENTS:

Tax Administrator Larry Warren will present the Monthly Collections Report and be available for questions and discussion.

The report is for information only; therefore, no action is required.

Monthly Collections Report

Watauga County

Bank deposits of the following amounts have been made and credited to the account of Watauga County. The reported
totals do not include small shortages and overages reported to the Watauga County Finance Officer

Monthly Report February 2018

	Current Month Collections	Current Month Percentage	Current FY Collections	Current FY Percentage	Previous FY Percentage
General County					
Taxes 2017	623,199.40	32.77%	29,587,111.15	95.96%	95.17%
Prior Year Taxes	21,479.50		305,275.31		
Solid Waste User Fees	58,014.08	27.80%	2,432,360.58	94.75%	93.43%
Green Box Fees	349.71	NA	5,275.81	NA	NA
Total County Funds	**$703,042.69**		**$32,330,022.85**		
Fire Districts					
Foscoe Fire	10,087.82	39.46%	442,354.18	96.72%	95.74%
Boone Fire	17,369.85	35.57%	856,173.28	96.56%	95.30%
Fall Creek Service Dist.	1,020.44	70.71%	9,293.54	95.92%	88.92%
Beaver Dam Fire	2,392.00	22.94%	94,940.46	92.32%	92.48%
Stewart Simmons Fire	5,335.40	29.54%	205,947.03	94.33%	93.34%
Zionville Fire	3,477.46	30.46%	106,464.59	93.79%	92.98%
Cove Creek Fire	4,320.52	24.43%	223,219.60	94.45%	93.83%
Shawneehaw Fire	4,184.82	48.06%	90,913.21	95.41%	95.70%
Meat Camp Fire	4,632.12	22.75%	197,930.89	93.18%	91.76%
Deep Gap Fire	5,167.67	35.05%	176,113.10	95.16%	94.44%
Todd Fire	1,620.78	35.65%	58,802.56	95.34%	95.10%
Blowing Rock Fire	8,257.61	27.28%	450,200.24	95.46%	95.56%
M.C. Creston Fire	635.70	45.43%	5,961.71	91.11%	85.21%
Foscoe Service District	982.80	25.50%	69,527.91	96.40%	96.81%
Beech Mtn. Service Dist.	1.10	0.05%	993.38	59.61%	97.33%
Cove Creek Service Dist.	0.00	0.00%	324.15	100.00%	100.00%
Shawneehaw Service Dist	168.78	10.74%	6,056.90		75.50%
	$68,634.43		**$2,985,923.19**		
Towns					
Boone	89,464.10	39.30%	5,798,326.06	97.74%	96.63%
Municipal Services	1,338.46	11.58%	125,800.67	92.66%	93.98%
Boone MV Fee	NA	NA	NA	NA	NA
Blowing Rock	NA	NA	NA	NA	NA
Seven Devils	NA	NA	NA	NA	NA
Beech Mountain	NA	NA	NA	NA	NA
Total Town Taxes	**$90,802.56**		**$5,924,126.73**		
Total Amount Collected	**$862,479.68**		**$41,240,072.77**		

Mitzi Rochelle Tax Collections Director

Tax Administrator

AGENDA ITEM 7:

TAX MATTERS

B. Refunds and Releases

MANAGER'S COMMENTS:

Mr. Warren will present the Refunds and Releases Report. Board action is required to accept the Refunds and Releases Report.

OWNER NAME AND ADDRESS	CAT YEAR PROPERTY REASON	BILL	EFF DATE JUR	REF NO	VALUE	CHARGE	AMOUNT
1760592 BODENHAMER, DAVID W. 2042 BROWNS CHAPEL RD BOONE, NC 28607	PP 2017 1704 TAX RELEASES ADJUSTED VALUE ON PERM TAG TRAILER	838	02/28/2018 F10	6403	7,720	F10 G01	3.86 27.25 31.11
1768517 BOYLES, VICKI LEE 425 ROXANNA STREET BOONE, NC 28607	PP 2017 2353 TAX RELEASES INCORRECT GAP BILLING	1000174	02/28/2018 F09	6383	0	F09 G01	1.51 9.45 10.96
1766877 CORNERSTONE MISSIONARY BAPTIST CHURCH PO BOX 565 DEEP GAP, NC 28618	RE 2017 2950-39-0780-000 TAX RELEASES PROPERTY EXEMPT	47610	02/28/2018 F10	6405	0	F10 G01	12.90 91.07 103.97
1743552 CRUMPLER, GEORGE 109 OAK RIDGE DRIVE BOONE, NC 28607	PP 2017 1041 TAX RELEASES PAID IN MECKLENBURG COUNTY FOR 2017	482	02/28/2018 F12	6404	0	F12 G01	5.31 37.49 42.80
1581179 CURVES FOR WOMEN 114 CLEMENT ST SUITE 101 BOONE, NC 28607	PP 2015 581179999 TAX RELEASES out of business	2805	02/28/2018 C02	6401	0	G01 C02 G01L C02L	12.99 17.02 1.30 1.70 33.01
1581179 CURVES FOR WOMEN 114 CLEMENT ST SUITE 101 BOONE, NC 28607	PP 2016 581179999 TAX RELEASES out of business	2942	02/28/2018 C02	6399	0	G01 C02	12.80 16.77 29.57
1581179 CURVES FOR WOMEN 114 CLEMENT ST SUITE 101 BOONE, NC 28607	PP 2017 581179999 TAX RELEASES out of business	3033	02/28/2018 C02	6398	0	G01 C02	14.44 16.77 31.21
1514803 ECKERD CORPORATION DBA RITE AID PO BOX 839 RITE AID STORE #11545 CAMP HILL, PA 17001-0839	PP 2017 514803999 TAX RELEASES REGISTERED IN TN FOR ONE YEAR	2368	02/28/2018 C02	6395	1,920	G01 C02	6.78 7.87 14.65
1514803 ECKERD CORPORATION DBA RITE AID PO BOX 839 RITE AID STORE #11545 CAMP HILL, PA 17001-0839	PP 2017 514803999 TAX RELEASES REGISTERED IN TN FOR ONE YEAR Reversal of release 6395	2368	02/28/2018 C02	6396	-1,920	G01 C02	-6.78 -7.87 -14.65

OWNER NAME AND ADDRESS	CAT PROPERTY REASON	YEAR	BILL	EFF DATE	JUR	REF NO	VALUE	CHARGE	AMOUNT
1395276 GRAGG, RUBY M	RE	2017	3148	02/28/2018			59,100	F12	29.55
119 VALLEY HIGH LN	1887-84-2235-000				F12			G01	208.62
	TAX RELEASES					6380			
BLOWING ROCK, NC 28605	FAILED TO RECEIVE OA EXEMPTION								238.17
1504563 HARMON, JIMMY CLYDE	PP	2017	2155	02/28/2018			0	F06	1.25
HARMON, DIANE	449789700				F06			G01	8.83
429 ROBY EGGERS RD	TAX RELEASES					6384		SWF	160.00
	SOLD MH IN 2016 MOVED TO WILKESBORO							F06L	.13
ZIONVILLE, NC 28698-9341								G01L	.88
									171.09
1504563 HARMON, JIMMY CLYDE	PP	2017	2155	02/28/2018			0	F06	-1.25
HARMON, DIANE	449789700				F06			G01	-8.83
429 ROBY EGGERS RD	TAX RELEASES					6385		SWF	-160.00
	SOLD MH IN 2016 MOVED TO WILKESBORO							F06L	-.13
ZIONVILLE, NC 28698-9341	Reversal of release 6384							G01L	-.88
									-171.09
1504563 HARMON, JIMMY CLYDE	PP	2017	2155	02/28/2018			500	F06	.25
HARMON, DIANE	449789700				F06			G01	1.77
429 ROBY EGGERS RD	TAX RELEASES					6386			
	SOLD BOAT IN 2016								2.02
ZIONVILLE, NC 28698-9341									
1504563 HARMON, JIMMY CLYDE	PP	2017	2155	02/28/2018			-500	F06	-.25
HARMON, DIANE	449789700				F06			G01	-1.77
429 ROBY EGGERS RD	TAX RELEASES					6388			
	SOLD BOAT IN 2016								-2.02
ZIONVILLE, NC 28698-9341	Reversal of release 6386								
1504563 HARMON, JIMMY CLYDE	PP	2017	2155	02/28/2018			1,500	F06	.75
HARMON, DIANE	449789700				F06			G01	5.30
429 ROBY EGGERS RD	TAX RELEASES					6389		SWF	80.00
	SOLD BOAT AND MH IN 2016								
ZIONVILLE, NC 28698-9341									86.05
1737405 MCGUINN, DAVID PATRICK	PP	2017	1000189	02/28/2018			1,920	F02	1.15
147 LITTLE LAUREL ROAD EX	2368				F02			G01	6.78
	TAX RELEASES					6397			
BOONE, NC 28607-8914	REGISTERED IN TN FOR ONE YEAR								7.93

OWNER NAME AND ADDRESS	CAT YEAR PROPERTY REASON	BILL	EFF DATE JUR	REF NO	VALUE	CHARGE	AMOUNT
1581348 MOUNTAIN DAWGS INC DBA TROLLY STOP 784 W KING ST BOONE, NC 28607	PP 2017 581348999 TAX RELEASES OUT OF BUSINESS	3040	02/28/2018 MS1	6402	0	C02 G01 MS1	42.11 36.25 21.57 99.93
1530175 PRESNELL, DAYTON C PRESNELL, BEN F C/O DELLA PRESNELL 1426 RAINBOW TRAIL BOONE, NC 28607	RE 2017 1941-83-3813-000 TAX RELEASES FAILED TO OA EXEMPTION	10452	02/28/2018 F03	6381	38,550	F03 G01	19.28 136.08 155.36
1749044 STARNES, MICHAEL 6163 EMORY LANE HICKORY, NC 28601	PP 2014 1238 TAX RELEASES BOUGHT AND MOVED CAMPER IN 2013	776	02/28/2018 F12	6390	0	F12 G01 SWF	4.24 26.54 80.00 110.78
1749044 STARNES, MICHAEL 6163 EMORY LANE HICKORY, NC 28601	PP 2015 1238 TAX RELEASES MH MOVED OUT OF CO 2013	715	02/28/2018 F12	6391	0	F12 G01 SWF F12L G01L	4.24 26.54 80.00 .42 2.65 113.85
1749044 STARNES, MICHAEL 6163 EMORY LANE HICKORY, NC 28601	PP 2016 1238 TAX RELEASES MH MOVED OUT OF CO 2013	648	02/28/2018 F12	6393	0	F12 G01 SWF F12L G01L	4.24 26.54 80.00 .42 2.65 113.85
1749044 STARNES, MICHAEL 6163 EMORY LANE HICKORY, NC 28601	PP 2017 1238 TAX RELEASES MH MOVED OUT OF COUNTY 2013	589	02/28/2018 F12	6394	0	F12 G01 SWF	4.12 29.05 80.00 113.17
DETAIL SUMMARY	COUNT: 22		RELEASES - TOTAL		108,790		1,321.72

RELEASES - CHARGE SUMMARY FOR ALL CLERKS

YEAR	CAT	CHARGE		AMOUNT
2014	PP	F12	BLOWING ROCK FIRE PP	4.24
2014	PP	G01	WATAUGA COUNTY PP	26.54
2014	PP	SWF	SOLID WASTE USER FEE	80.00
			2014 TOTAL	110.78
2015	PP	C02	BOONE PP	17.02
2015	PP	C02L	BOONE LATE LIST	1.70
2015	PP	F12	BLOWING ROCK FIRE PP	4.24
2015	PP	F12L	BLOWING ROCK FIRE LATE LIST	.42
2015	PP	G01	WATAUGA COUNTY PP	39.53
2015	PP	G01L	WATAUGA COUNTY LATE LIST	3.95
2015	PP	SWF	SANITATION USER FEE	80.00
			2015 TOTAL	146.86
2016	PP	C02	BOONE PP	16.77
2016	PP	F12	BLOWING ROCK FIRE PP	4.24
2016	PP	F12L	BLOWING ROCK FIRE LATE LIST	.42
2016	PP	G01	WATAUGA COUNTY PP	39.34
2016	PP	G01L	WATAUGA COUNTY LATE LIST	2.65
2016	PP	SWF	SANITATION USER FEE	80.00
			2016 TOTAL	143.42
2017	RE	F03	FALL CREEK FIRE DISTRICT	19.28
2017	RE	F10	DEEP GAP FIRE RE	12.90
2017	RE	F12	BLOWING ROCK FIRE RE	29.55
2017	RE	G01	WATAUGA COUNTY RE	435.77
2017	PP	C02	BOONE PP	58.88
2017	PP	F02	BOONE FIRE PP	1.15
2017	PP	F06	ZIONVILLE FIRE PP	.75
2017	PP	F06L	ZIONVILLE FIRE LATE LIST	.00
2017	PP	F09	MEAT CAMP FIRE PP	1.51
2017	PP	F10	DEEP GAP FIRE PP	3.86
2017	PP	F12	BLOWING ROCK FIRE PP	9.43
2017	PP	G01	WATAUGA COUNTY PP	166.01
2017	PP	G01L	WATAUGA COUNTY LATE LIST	.00
2017	PP	MS1	BOONE MUNICIPAL SERV DIST PP	21.57
2017	PP	SWF	SANITATION USER FEE	160.00
			2017 TOTAL	920.66
			SUMMARY TOTAL	1,321.72

RELEASES - JURISDICTION SUMMARY FOR ALL CLERKS

JUR	YEAR	CHARGE		AMOUNT
C02	2015	C02	BOONE PP	17.02
C02	2015	C02L	BOONE LATE LIST	1.70
C02	2015	G01	WATAUGA COUNTY PP	12.99
C02	2015	G01L	WATAUGA COUNTY LATE LIST	1.30
C02	2016	C02	BOONE PP	16.77
C02	2016	G01	WATAUGA COUNTY PP	12.80
C02	2017	C02	BOONE PP	16.77
C02	2017	G01	WATAUGA COUNTY PP	14.44
			C02 TOTAL	93.79
F02	2017	F02	BOONE FIRE PP	1.15
F02	2017	G01	WATAUGA COUNTY PP	6.78
			F02 TOTAL	7.93
F03	2017	F03	FALL CREEK FIRE DISTRICT	19.28
F03	2017	G01	WATAUGA COUNTY RE	136.08
			F03 TOTAL	155.36
F06	2017	F06	ZIONVILLE FIRE PP	.75
F06	2017	F06L	ZIONVILLE FIRE LATE LIST	.00
F06	2017	G01	WATAUGA COUNTY PP	5.30
F06	2017	G01L	WATAUGA COUNTY LATE LIST	.00
F06	2017	SWF	SANITATION USER FEE	80.00
			F06 TOTAL	86.05
F09	2017	F09	MEAT CAMP FIRE PP	1.51
F09	2017	G01	WATAUGA COUNTY PP	9.45
			F09 TOTAL	10.96
F10	2017	F10	DEEP GAP FIRE PP	16.76
F10	2017	G01	WATAUGA COUNTY PP	118.32
			F10 TOTAL	135.08
F12	2014	F12	BLOWING ROCK FIRE PP	4.24
F12	2014	G01	WATAUGA COUNTY PP	26.54
F12	2014	SWF	SOLID WASTE USER FEE	80.00
F12	2015	F12	BLOWING ROCK FIRE PP	4.24
F12	2015	F12L	BLOWING ROCK FIRE LATE LIST	.42
F12	2015	G01	WATAUGA COUNTY PP	26.54
F12	2015	G01L	WATAUGA COUNTY LATE LIST	2.65
F12	2015	SWF	SANITATION USER FEE	80.00
F12	2016	F12	BLOWING ROCK FIRE PP	4.24
F12	2016	F12L	BLOWING ROCK FIRE LATE LIST	.42
F12	2016	G01	WATAUGA COUNTY PP	26.54
F12	2016	G01L	WATAUGA COUNTY LATE LIST	2.65
F12	2016	SWF	SANITATION USER FEE	80.00
F12	2017	F12	BLOWING ROCK FIRE RE	38.98
F12	2017	G01	WATAUGA COUNTY RE	275.16
F12	2017	SWF	SANITATION USER FEE	80.00

RELEASES - JURISDICTION SUMMARY FOR ALL CLERKS

JUR	YEAR	CHARGE		AMOUNT
			F12 TOTAL	732.62
MS1	2017	C02	BOONE PP	42.11
MS1	2017	G01	WATAUGA COUNTY PP	36.25
MS1	2017	MS1	BOONE MUNICIPAL SERV DIST PP	21.57
			MS1 TOTAL	99.93
			SUMMARY TOTAL	1,321.72

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AGENDA ITEM 8:

MISCELLANEOUS ADMINISTRATIVE MATTERS

A. Boards and Commissions

MANAGER'S COMMENTS:

WAMY Community Action

Ms. Joy Coffey's final term as a Public Sector representative for Watauga County ended on February 8, 2018. Ms. Melissa Soto, Executive Director of WAMY, has requested a Commissioner or appointee be appointed to fill one four-year term. A volunteer application has been received from Mr. George Winkler who has expressed interest in serving.

Ms. Soto has stated that the WAMY Board meets bi-monthly on the 2nd Tuesday at 5:00 P.M. The meetings are held in the Commissioners' Board Room in Avery County. The next meeting is their Board Retreat (and a great time for a new member to begin) which will be held in the Boone office on April 7 at 10:00 A.M. The next regular meeting will be May 8.

Volunteer Application
Watauga County Boards And Commissions

If you are a Watauga County resident, at least 18 years old, and willing to volunteer your time and expertise to your community, please complete the application below and click on Print Form. Please sign and mail or fax to:

Watauga County Commissioners' Office
814 West King Street, Suite 205
Boone, NC 28607
Phone: (828) 265-8000
Fax: (828) 264-3230

Name: George Winkler

Home Address: 427 Winklers Creek Rd

City: Boone Zip: 28607

Telephone: (H) 828-264-2943 (W) 828-406-0871 (Fax) _____

Email: georgewinkler@bellsouth-Net

Place of Employment: Self Employed @ New River Farms Apts

Job Title: Owner / Manager

In Order To Assure County wide Representation Please Indicate Your Township Of Residence:

( ) Bald Mountain	( ) Stony Fork	( ) Watauga
( ) New River	( ) Brushy Fork	( ) Cove Creek
( ) Beaver Dam	( ) Meat Camp	( ) Shawneehaw
( ) Blue Ridge	( ) Blowing Rock	( ) Laurel Creek
( ) Elk	( ) North Fork	(X) Boone

In addition, Please Indicate If You Live In One Of The Following Areas:

( ) Foscoe-Grandfather Community	( ) Valle Crucis Historic District
( ) Howards Creek Watershed	( ) Winklers Creek Watershed
( ) South Fork New River Watershed	( ) Extraterritorial Area

We Ask Your Help In Assuring Diversity Of Membership By Age, Gender, And Race, By Answering The Following Questions

Gender	Ethnic Background	
(X) Male	( ) African American	( ) Hispanic
( ) Female	(X) Caucasian	( ) Other
	( ) Native American	

Please List (In Order Of Preference) The Boards/Commissions On Which You Would Be Willing To Serve.

1. Non-Profit
2.
3.

Volunteer Application
Watauga County Boards And Commissions
(Continued)

Please list any work, volunteer, and/or other experience you would like to have considered in the review of your application.

Work Experience:

- Property Manager for 20 Tenants

Volunteer Experience:

- Member of Masonic Snow Lodge # 363 (Past Master)
- Member & treasurer of the Appalachian Shrine Club
- Member, driver & treasurer of High Country Visually Impaired Support Group
- Harbin Park School treasurer (Past)

Other Experience:

Other Comments:

- would enjoy helping my community through W.A.M.G.

Signature: _____ Date: 3-14-18

Print Form | Reset Form

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AGENDA ITEM 8:

MISCELLANEOUS ADMINISTRATIVE MATTERS

B. Announcements

MANAGER'S COMMENTS:

Watauga County Planning & Inspections, Veteran's Service Office, and the Red Cross Office are moving on Wednesday, March 21, 2018, to the 2nd Floor of the Health Department Building located at 126 Poplar Grove Connector. The entrance to these offices will be at the lower level on the side facing the Humane Services Building (Social Services/Project on Aging).

Watauga County
Planning & Inspections/
Veteran's Service/Red Cross

WE ARE MOVING

March 21, 2018

to

126 Poplar Grove Connector

2nd Floor

(Health Department Building)

Our entrance will be at the lower level,

side facing Social Services/Project on Aging Building

(This will prevent you having to go through clinic waiting area)

AGENDA ITEM 9:

PUBLIC COMMENT

AGENDA ITEM 10:

BREAK

AGENDA ITEM 11:

CLOSED SESSION

Attorney/Client Matters – G. S. 143-318.11(a)(3)
Land Acquisition – G. S. 143-318.11(a)(5)(i)
Personnel Matters – G. S. 143-318.11(a)(6)

AGENDA ITEM 12:

POSSIBLE ACTION AFTER CLOSED SESSION