

COUNTY OF DARE

PO Box 1000, Manteo, NC 27954

#### DARE COUNTY BOARD OF COMMISSIONERS

Dare County Administration Building 954 Marshall C. Collins Dr., Manteo, NC

#### Monday, May 07, 2018

#### "HOW WILL THESE DECISIONS IMPACT OUR CHILDREN AND FAMILIES?"

#### AGENDA

#### 9:00 AM CONVENE, PRAYER, PLEDGE OF ALLEGIANCE

- ITEM 1 Opening Remarks Chairman's Update
- **ITEM 2** Presentation of County Service Pins
- **ITEM 3** Employee of the Month
- ITEM 4 Public Comments
- **ITEM 5** Report from Outer Banks Sporting Events
- **ITEM 6** Public Health Division Presentation on Adult Day Care
- **ITEM 7** Dare County Public Health Division Lease with Port Human Services
- **ITEM 8** Roanoke Shores Homeowners Association -- Proposed RS-8 Zoning Text Amendment
- ITEM 9 J. D. Johnson Realty- Wanchese Zoning Map Amendment
- **ITEM 10** System Development Fee Calculation Required by NCGS 162A Article 8
- **ITEM 11** Series 2018 Limited Obligation Bonds Decision on Issuance Type, Structure, and Financing Award
- **ITEM 12** Interlocal Agreement County of Dare and the Town of Nags Head
- **ITEM 13** Resolution Requesting Funding of the Coastal Storm Damage Mitigation Fund
- **ITEM 14** Letter of Support for Town of Kitty Hawk Grant Application
- **ITEM 15** NCDOT Right of Way and Utility Easement
- **ITEM 16** Civil Complaint Seeking Remedies Against Those Responsible for the Opioid Crisis

- ITEM 17 Consent Agenda
  - 1. Approval of Minutes (04.16.18 & Budget Workshop)
  - 2. Detention Center Willo Service Contract for Mechanical Doors
  - 3. Detention Center Thyssen Krupp Service Contract for Elevator
- **ITEM 18** Board Appointments
  - 1. Extra Territorial Jurisdiction (ETJ) District (Town of Nags Head)
  - 2. Zoning Board of Adjustment Dare
  - 3. Upcoming Board Appointments
- **ITEM 19** Commissioners' Business & Manager's/Attorney's Business

ADJOURN UNTIL 5:00 P.M. ON MAY 21, 2018



**Opening Remarks - Chairman's Update** 

### Description

Dare County Chairman Robert Woodard will make opening remarks.

### **Board Action Requested**

Informational Presentation

### **Item Presenter**

Chairman Robert Woodard



Presentation of County Service Pins

### Description

The following employees are scheduled to receive service pins this month:

- Scott Powers, Deputy Sheriff Master Officer, 10 Year Pin
   Joseph Shull, Detention Officer, 10 Year Pin
- 3. Tim White, Public Services Director, 10 Year Pin

### **Board Action Requested**

None

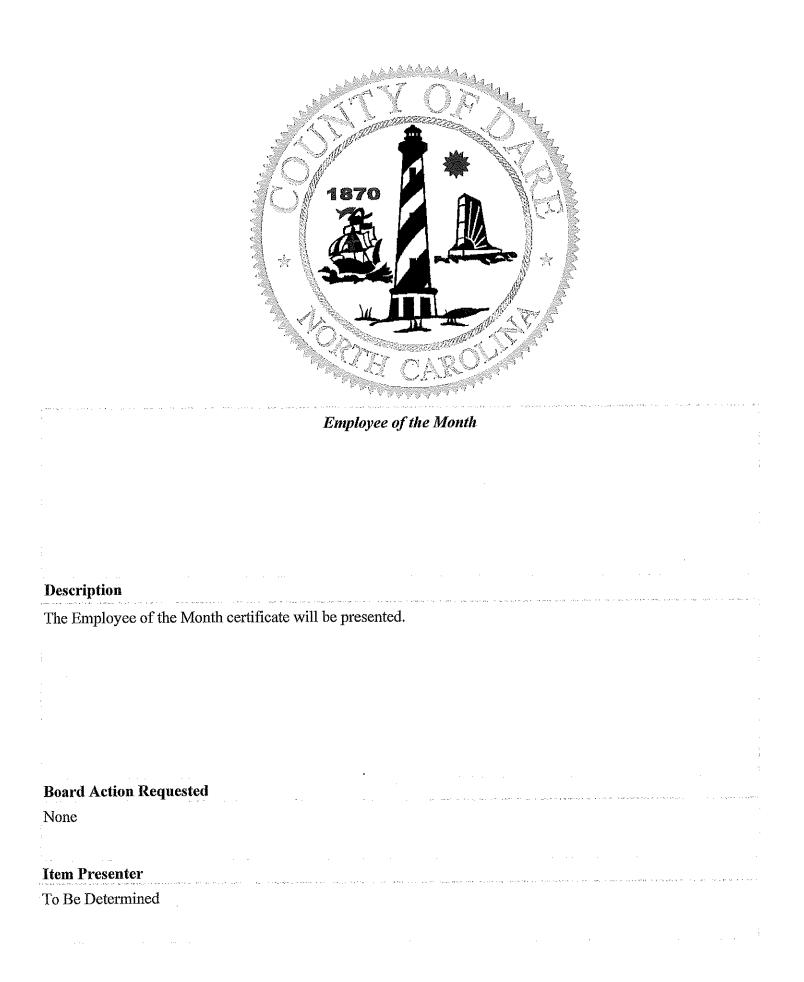
### **Item Presenter**

Robert Outten, County Manager

May 2018

### **Presentation of County Service Pins**

- Scott Powers, Deputy Sheriff Master Officer, 10 Year Pin
   Presented by Doug Doughtie
- Joseph Shull, Detention Officer, 10 Year Pin
   -Presented by Allen Moran
- Tim White, Public Services Director, 10 Year Pin
   -Presented by Bobby Outten





**Public Comments** 

### Description

The Board of Commissioners will provide time on the agenda for Public Comments. Each regularly scheduled meeting begins with an opportunity for anyone to speak directly to the entire Board of Commissioners for up to five minutes on any topic or item of concern.

In an effort to encourage public participation, the Board accepts public comments from 2 locations - - -

Public Comments can be made at the Commissioners Meeting Room in Manteo. Public Comments can be made via a video link at the Fessenden Center in Buxton.

#### **Board Action Requested**

Hear Public Comments

#### **Item Presenter**

Robert Outten, County Manager



**Report from Outer Banks Sporting Events** 

### Description

Outer Banks Sporting Events (OBSE) will give an update report on the economic impact of OBSE events and outline their upcoming activities.

#### **Board Action Requested**

None - Informational Presentation

### **Item Presenter**

Ray Robinson, Executive Director Jenny Ash, Race Director

# **2018 Partner Report**

## **Outer Banks Sporting Events**

11

Kill Devil Hills, North Carolina

The Marathon began in 2006 + OBSE was created in 2010

### 4 part mission

The mission of Outer Banks Sporting Events is <sup>1</sup> to organize and promote sports competition <sup>2</sup> and healthy living,

to<sup>3</sup>provide financial resources for needed relief and support for public education  $_4$  while contributing to economy of the Outer Banks of North Carolina.



## **MEETING THE MISSION IN 2017**

### **Organizing Sports Competitions**

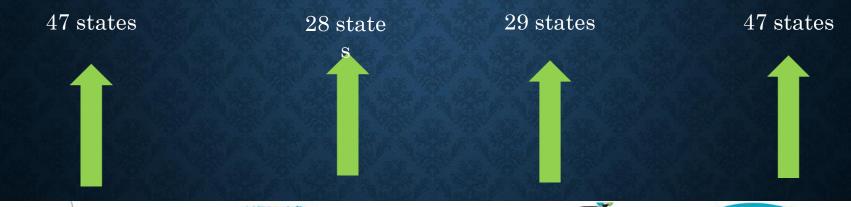
- Total Participants
- Their Guests
- Runner Gender
   55% Female / 45% Male
  - Runner Average Age 35-45
  - % Visitor
    - 87% (23% are 1<sup>st</sup> time visitors)







## WHERE WERE OUR 2017 REGISTRANTS FROM? ALL 50 STATES WERE REPRESENTED





## **18 COUNTRIES WERE REPRESENTED**

Afghanistan Albania Canada France Albania Kenya Norway Algeria Cape Verde

Uruguay China Antigua Morocco New Zealand Russia St. Helena UK USA



## OUR RACES ENCOURAGE HEALTHY LIFESTYLES HERE



1,146 of registrants were local

that's 3% of Dare County residents

<u>The Outer Banks Hospital</u> sponsors a "Couch to 5K" challenge at the Flying Pirate in the spring

## SUPPORTING OUR FOUNDING CHARITIES



In 2017 OBSE generated just over **\$50,000** for each organization

Since 2010 OBSE has generated **\$1,000,151** for each charity



ON THE EASI COASI **3 DISTANCES** Sprint 750 M | 12.5 MI | 5K Olympic 1500 M | 24.5 MI | 10K Half 1.2 MI | 56 MI | 13.1 MI

AWARDS | FOOD & BEER | MEDALS









RACE OUTER BANKS FLYING PIRATE HALF MARATHON APRIL 14-15, 2018

STER TODAY



VETERANS DAY WEEKEND NOV. 9-11, 2018



JUNE 17, 2018

## 2017 ESTIMATED ECONOMIC IMPACT FOR DARE COUNTY \$ MILLION

- 7053 Participants x 3.2 guests each (22,570)=
- 29,620 Visitors @ \$75. per day x 2.7 days=
- \$6. M Per Diem Total
- \$2.4 M Accommodations

ESTIMATED \$8.4 M total economic impact

Data comes from registrants' self-reporting at time of registratio n

## THANK YOU

Dare County cooperation is vital to Outer Banks Sporting Events.

20



Jenny Ash **Race Director** 255-6273 jenny@obxse.org

**Ray Robinson Executive Director** 255-6273 ray@obxse.org



### DARE COUNTY DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH DIVISION ADULT DAY CARE

### Description

Presentation on Adult Day Care.

### **Board Action Requested**

N/A

### **Item Presenter**

Sheila F. Davies, PhD and Kaye White.

## Adult Day Care Overview

Kaye White Senior Tar Heel Legislature Delegate

Sheila F. Davies, PhD Director of Public Health



## **Adult Dare Care Centers**

- Adult day service centers provide a coordinated program of professional and compassionate services for adults in a community-based group setting.
- Services are designed to provide social and some health services to adults who need supervised care in a safe place outside the home during the day.
- They also afford caregivers respite from the demanding responsibilities of caregiving.



# Adult Day Care Models

- Social provides meals, recreation and some health-related services
- Medical/health provides social activities as well as more intensive health and therapeutic services
- Specialized provide services only to specific care recipients, such as those with diagnosed dementias or developmental disabilities.



# **Adult Day Care Centers**

- Social activities interaction with other participants in planned activities appropriate for their conditions
- Meals and snacks participants are provided with meals and snacks, those with special dietary needs are offered special meals
- Personal care help with toileting, grooming, eating and other personal activities of daily living
- Therapeutic activities exercise and mental interaction for all participants
- Transportation (optional) door-to-door service



# **Adult Day Care Centers**

- Estimated more than 5,000 centers operating in the U.S. serving 150,000 individuals each day
  - 95 certified centers in NC among 47 counties
- Nearly 78 percent of adult day centers are operated on a nonprofit or public basis and the remaining 22 percent are for profit.
  - ▶ 86% of centers in NC are nonprofit
- 70 percent of adult day centers are affiliated with larger organizations such as home care, skilled nursing facilities, medical centers, or multi-purpose senior organizations.
- The average age of the adult day center care recipient is 72



# **Adult Day Care Centers**

- Thirty-five percent of the adult day center care recipients live with an adult child, 20% with a spouse, 18% in an institutional setting, 13% with parents or other relatives, while 11% live alone.
- Fifty-two percent of the adult day center care recipients using adult day services centers nationwide have some cognitive impairment.
  - 75% of NC centers provide specific program for Alzheimer's patients or other dementias
- The average capacity of adult day centers is 40.
- The average adult day center care recipient to staff ratio is 6:1.



## Adult Day Care Funding

- Funding for adult day services is fragmented, from multiple sources, including fees for service and third party payers, as well as public and philanthropic sources.
  - Medicare (home health and therapy)
  - Medicaid waiver programs, including personal care
  - Private/out of pocket
  - Older Americans Act (Title III)
  - Social Services Block Grants (Title XX)
  - Child and Adult Care Food Programs
  - Veterans Administration
  - Budgeted state-specific funding
  - Local tax levies
  - Long-term care insurance plans



County of Dare Department of Health & Human Services

# Adult Day Care Funding

- Daily fees for adult day services vary depending upon the services provided. The national average rate for adult day centers is \$61 per day (includes 8-10 hours on average)
- National average rate for home health contract aid is \$19/hour
- NC Division Aging and Adult Services strongly advises that operators assess their ability to sustain adult day care programs without State or Federal funding
  - ""Although there is a need for services to keep our elderly and disabled citizens in their homes, there is unfortunately little funding to support this goal"



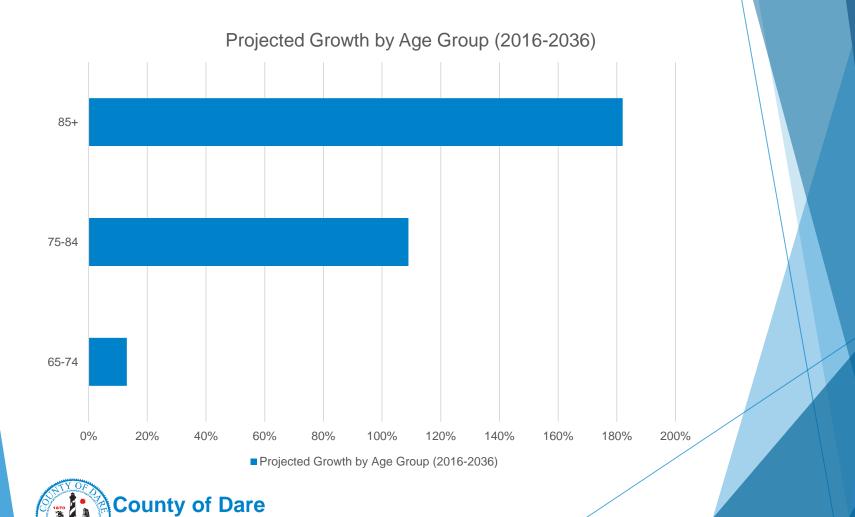
## Dare County Aging Profile 2016 - 2036

Ages	2016		2036		% Change (20	
	#	%	#	%	years)	
Total	36	,387	40, <sup>-</sup>	792	12%	
0-17	6,901	19%	7,358	18%	7%	
18-44	11.159	31%	11,824	29%	6%	
45-59	8,147	22%	7,930	19%	-3%	
60+	10,180	28%	13,680	34%	34%	
65+	7,227	20%	11,232	28%	55%	
85+	641	2%	1,810	4%	182%	



**County of Dare** Department of Health & Human Services

# **Aging Population**



Department of Health & Human Services

## Dare County Adult Day Center Need Survey

## 144 respondents

- 66 (46%) currently in caregiver role
- 102 (73%) expect to be in caregiver role in future
- 117 (82%) of respondents are age 50 or older
  - 43 Caring for person age between 66-80
  - 41 Caring for person over age 81



# Dare County Adult Day Center Need Survey

- 127 (93%) responded it would be important/very important to have a Medical Adult Day Care Center in Dare
- 129 (95%) responded it would be important/very important to have a Social Adult Day Care Center in Dare
- Transportation/Travel
  - > 92 (79%) could provide their own transportation
  - Majority willing to travel 5 25 miles
- Willingness to Pay
  - 73 (55%) Yes
  - 60 (45%) No
  - 76 (60%) would need some financial assistance



## Considerations

- Needs/Demand Assessment
- Availability of Funding Sources/Revenue Streams
- Partnership

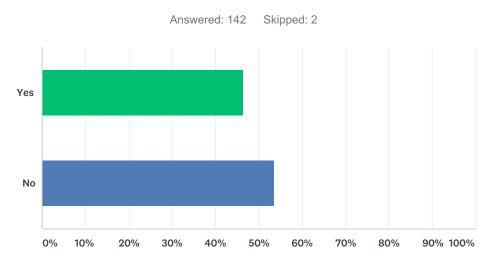
The North Carolina Adult Day Services Association estimates average annual operating budget of minimum of \$150,000 for centers serving between 20 – 25 participants with start up costs ranging from \$80,000 - \$150,000



# **Questions?**

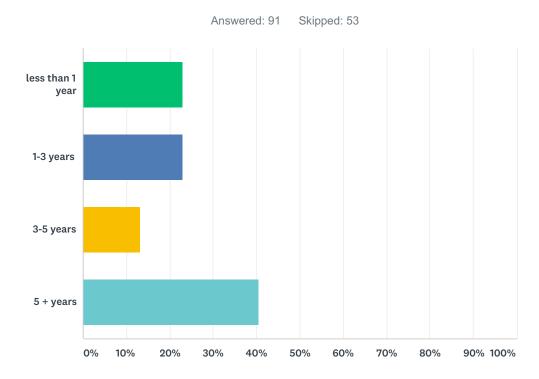


## Q1 Are you currently a caregiver for a family member or a friend?



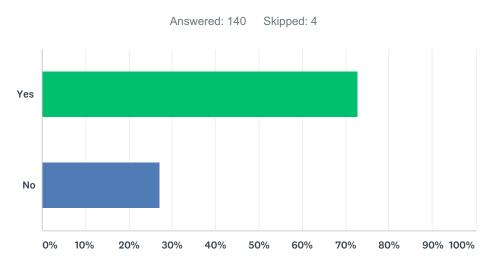
ANSWER CHOICES	RESPONSES	
Yes	46.48%	66
No	53.52%	76
TOTAL		142

### Q2 How long have you been a caregiver for a family member or friend?



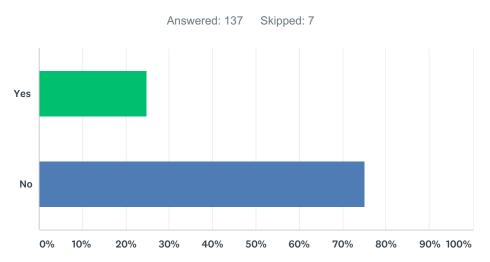
ANSWER CHOICES	RESPONSES	
less than 1 year	23.08%	21
1-3 years	23.08%	21
3-5 years	13.19%	12
5 + years	40.66%	37
TOTAL		91

## Q3 Do you expect to be a caregiver for a family member or friend in the future?

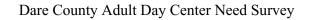


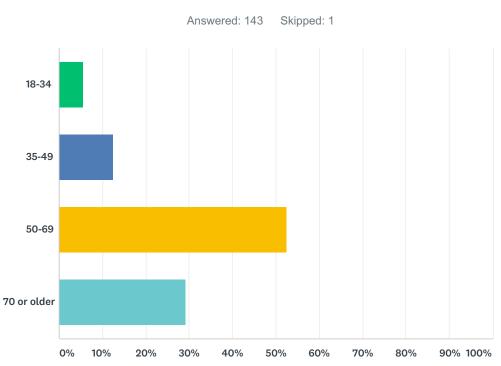
ANSWER CHOICES	RESPONSES	
Yes	72.86%	102
No	27.14%	38
TOTAL		140

### Q4 Do you consider yourself a long-distance caregiver?



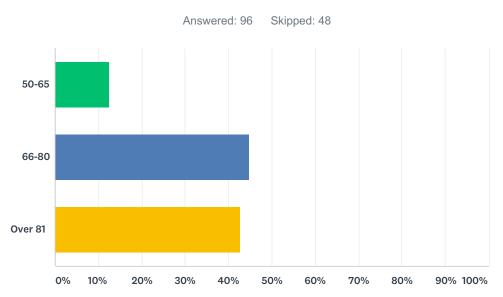
ANSWER CHOICES	RESPONSES	
Yes	24.82%	34
No	75.18%	103
TOTAL		137





ANSWER CHOICES	RESPONSES	
18-34	5.59%	8
35-49	12.59% 1	8
50-69	52.45% 7	75
70 or older	29.37% 4	12
TOTAL	14	3

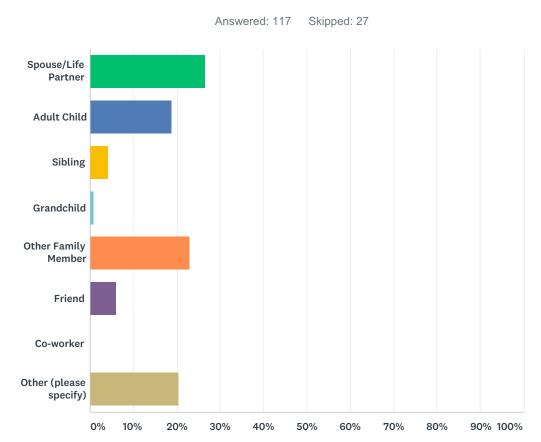
## Q5 What is your age group?



## Q6 What is the age of the person you care for?

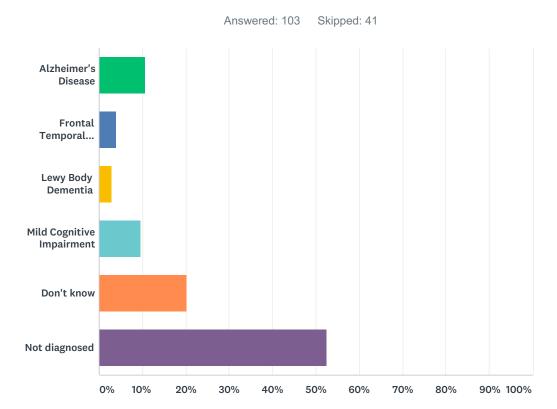
ANSWER CHOICES	RESPONSES	
50-65	12.50%	12
66-80	44.79%	43
Over 81	42.71%	41
TOTAL		96

## Q7 What is your relationship to the person you care for or may care for in the future?



ANSWER CHOICES	RESPONSES	
Spouse/Life Partner	26.50%	31
Adult Child	18.80%	22
Sibling	4.27%	5
Grandchild	0.85%	1
Other Family Member	23.08%	27
Friend	5.98%	7
Co-worker	0.00%	0
Other (please specify)	20.51%	24
TOTAL		117

### Q8 If your family member/friend has dementia, do you know the type?

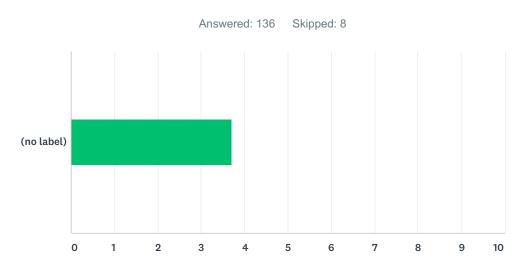


ANSWER CHOICES	RESPONSES	
Alzheimer's Disease	10.68%	11
Frontal Temporal Dementia	3.88%	4
Lewy Body Dementia	2.91%	3
Mild Cognitive Impairment	9.71%	10
Don't know	20.39%	21
Not diagnosed	52.43%	54
TOTAL		103

## Q9 If your family member/friend needs care for something different, please indicate.

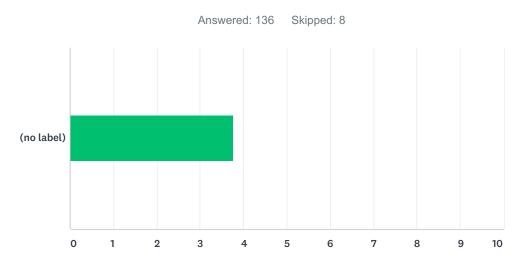
Answered: 40 Skipped: 104

Q10 How important would it be to have a Medical Model Adult Day Center? (A medical model adult day center means the provision of group care and supervision in a place other than their usual place of abode on a less than 24-hour basis to adults who may be physically or mentally disabled.



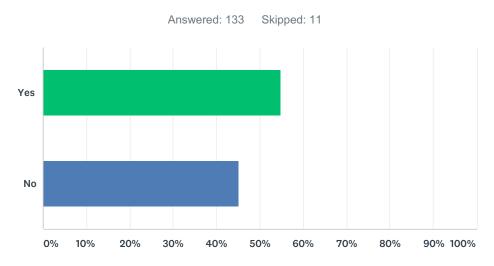
	NOT IMPORTANT	NEUTRAL	IMPORTANT	VERY IMPORTANT	DON'T KNOW	TOTAL	WEIGHTED AVERAGE	
(no label)	0.74% 1	2.94% 4	23.53% 32	69.85% 95	2.94% 4	136	3.7	1

Q11 How important would it be to have a Social Model Adult Day Center/Program? (a social model adult day center/program provides an organized program in a community group setting to promote social, physical and emotional well-being).



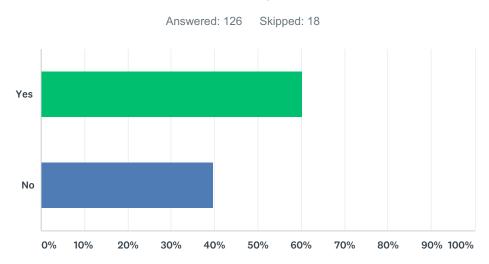
	NOT IMPORTANT	NEUTRAL	IMPORTANT	VERY IMPORTANT	DON'T KNOW	TOTAL	WEIGHTED AVERAGE	
(no label)	0.00% 0	2.21% 3	21.32% 29	73.53% 100	2.94% 4	136		3.77

Q12 Costs to consumers to attend Adult Day Center's vary but consistently these costs are lower than the cost of in-home (\$15-\$25, non-medical and higher for medical care) or facility costs (\$5,000-\$8,000 per month).There is limited funding from state and federal sources. Could you pay for the service if it was available in your area?



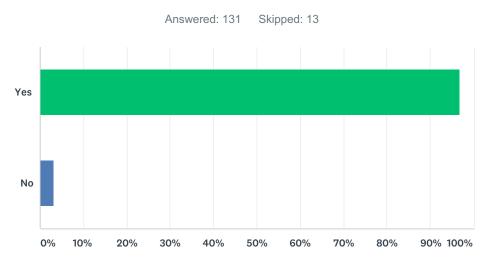
ANSWER CHOICES	RESPONSES	
Yes	54.89%	73
No	45.11%	60
TOTAL		133

## Q13 Would you need financial assistance to pay for Adult Day Services/Programs?



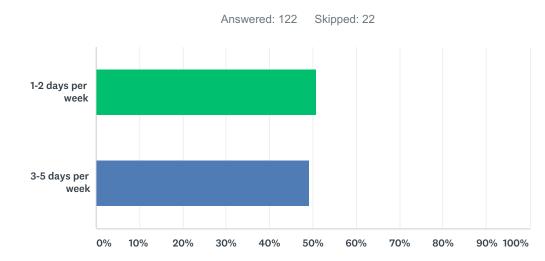
ANSWER CHOICES	RESPONSES	
Yes	60.32%	76
No	39.68%	50
TOTAL		126

### Q14 Typically Adult Day Center's operate from 8:00 a.m.-6:00 p.m. Would this time frame be appropriate for your needs?



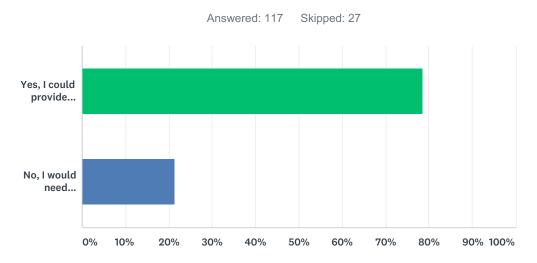
ANSWER CHOICES	RESPONSES	
Yes	96.95%	127
No	3.05%	4
TOTAL		131

## Q15 How often would you use the Adult Day Services/Program for your family member/friend you care for?



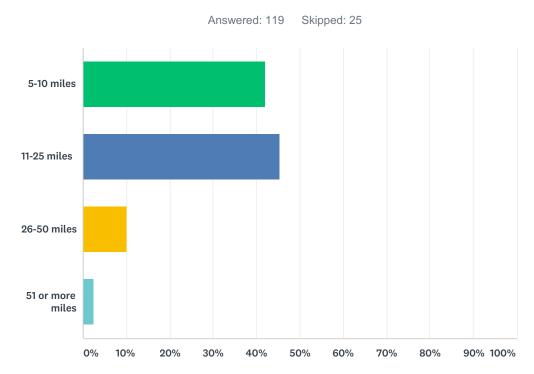
ANSWER CHOICES	RESPONSES	
1-2 days per week	50.82%	62
3-5 days per week	49.18%	60
TOTAL		122

### Q16 If an Adult Day Center was available in Dare County would you be able to transport your family member/friend to the center or would you need county transportation?



ANSWER CHOICES	RESPONSES	
Yes, I could provide transportation for my family member/friend.	78.63%	92
No, I would need transportation for my family member/friend.	21.37%	25
TOTAL		117

## Q17 If you were able to provide transportation for your family member/friend you care for, how far could you travel?



ANSWER CHOICES	RESPONSES	
5-10 miles	42.02%	50
11-25 miles	45.38%	54
26-50 miles	10.08%	12
51 or more miles	2.52%	3
TOTAL		119



Dare County Public Health Division - Lease with Port Human Services

#### Description

Lease with Port Human Services for property located at 57635 NC-12, Hatteras, NC.

#### **Board Action Requested**

Approve Lease

#### **Item Presenter**

Sheila F. Davies, PhD

#### STATE OF NORTH CAROLINA COUNTY OF DARE

#### **LEASE AGREEMENT**

**THIS LEASE AGREEMENT**, made and entered into this the 23<sup>rd</sup> day of January, 2018 by and between Dare County (hereinafter referred to as "Landlord"), and Port Health Services (hereinafter referred to as "Tenant".

#### W ITNESSETH:

In consideration of the mutual covenants and conditions as hereinafter set forth, the parties do appear agree as follows:

1. <u>LEASED PREMISES</u> - The Landlord hereby leases to Tenant, subject to the conditions hereinafter expressed, that certain parcel of real property, together with a section of the buildings and all improvements thereon having a physical address of: 57635 NC-12, Hatteras, NC 27953 (hereinafter the "Leased Premises"). Tenant acknowledges that other tenants may use portions of the improvements, parking and signage.

2. <u>TERM</u> - The term of this Lease shall be for three (3) years commencing on March 1, 2018 and continuing until February 28, 2021.

3. <u>RENT</u> –No rent shall be due by Tenant to Landlord for the Leased Premises.

4. <u>USE OF PREMISES</u> - Tenant shall use the Leased Premises for the purpose of providing behavioral health services. The Tenant shall not use or knowingly permit any part of the Leased Premises to be used for any unlawful purpose.

5. <u>WASTE OR NUISANCE</u> - Tenant shall not commit or suffer to be committed any waste upon the Leased Premises or any nuisance or other act or thing which may disturb the quiet or enjoyment of any other neighboring owner or tenant.

#### 6. <u>MAINTENANCE</u>:

- (a) General Tenant is assuming the Leased Premises "as is" and represents that it has inspected the premises and is satisfied with the condition thereof. Landlord shall perform maintenance necessary to maintain the premises in good condition, including, without limitation, the structure, the septic system, as well as the repairs to the HVAC systems serving the premises. Landlord shall be responsible to maintain the roof, foundation and exterior walls including glass; windows; doors; door closure devises; window and door frames, molding, locks, and hardware.
- (b) Maintenance of Equipment and furnishings owned by Tenant Tenant shall be responsible for the maintenance of any equipment that Tenant brings on to the Leased Premises including but not limited to computers, phones, electronic equipment and any furnishings.

- (c) Cleaning Tenant shall be responsible for any costs associated with the cleaning of the Leased Premises.
- (d) Tenant's sole remedy upon landlord's breach of the maintenance provision of this Agreement, is termination of the lease without further obligation of liability by either party or the other.

7. <u>RIGHT OF ENTRY</u> - Landlord shall have the right during normal business hours to enter the leased premises; (a) to inspect the general condition and state of repair thereof, (b) to make repairs required or permitted under this lease, or (c) for any other reasonable purpose.

8. <u>SURRENDER OF PREMISES</u> - The Tenant shall on the expiration or the sooner termination of the lease terms, surrender to the Landlord the Leased Premises, in the same condition in which said property was delivered into possession of Tenant, reasonable wear and tear expected.

#### 9. <u>TAXES AND UTILITIES:</u>

- (a) Utilities Landlord shall pay the charges for sewer, electricity, telephone and other services and utilities used by Tenant on the Leased Premises during the term of this Lease
- (b) <u>Ad Valorem Taxes</u> In that the County of Dare is the owner of the premises, there are no assessments for ad valorem taxes. In the event the property is sold, subject to this lease, Tenant shall be responsible for and shall pay before delinquency all ad valorem taxes with regard to the real property and equipment existing on the property during the term of this Lease.

10. <u>ASSIGNMENT AND SUBLEASE</u> – Tenant shall not assign or sublease all or any part of the Leased Premises without the written consent of the Landlord.

#### 11. <u>INSURANCE</u>

(a) Liability – Tenant hereby covenants and agrees to hold Landlord harmless from any loss, expense or damage for any injury or damage to any person or any property at any time on the demised premises or in the buildings or improvements thereon form any cause whatsoever which my arise from the use or occupancy of the premises or improvements by Tenant and shall carry, at its own expense, adequate public liability insurance on the premises for the protection and benefit of both Landlord and Tenant, which said insurance coverage shall be with a reputable carrier authorized to do business in the State of North Carolina, and shall provide protection to Landlord as a named insured. The policy shall be in an amount of not less than \$1,000,000.00 for any accident together with \$100,000.00 for property damage. Tenant shall name Landlord as an additional insured on such policies. Landlord shall be given copies of all policies.

(b) Hazard – Landlord may, if desired, at Landlord's expense, keep in full force and effect a general policy of hazard insurance, insuring loss or damage by fire and such other risks as

are now or hereinafter included in the extended coverage endorsements, including vandalism, explosion and malicious mischief coverage.

12. <u>ENTIRE AGREEMENT</u> – This Lease sets forth the covenants, promises, agreements, conditions and understandings between Landlord and Tenant concerning the Leased Premises and there are no covenants, promises, agreements, conditions or understandings, either oral or written, between them other than are herein set forth. Except as herein otherwise provided, no subsequent alteration, amendment, change or addition to this Lease shall be binding upon Landlord or Tenant unless reduced to writing and signed by them.

13. <u>NOTICES</u> – Any notice, demand, request or other instrument which may be or is required to be given under this Lease shall be delivered in person or sent by United States Certified Mail postage prepaid and shall be addressed to:

TENANT:

LANDLORD: Dare County P.O. Box 1000 Manteo, NC 27954 Attn. Robert L. Outten

**IN WITNESS WHEREOF**, the parties hereto have hereunder set their hands and seals all by authority duly given in duplicate originals the day and year first above written.

LANDLORD:

**TENANT:** 

DARE COUNTY

By: \_\_\_\_\_

By: \_\_\_\_\_



Roanoke Shores HOA- Proposed RS-8 Zoning Text Amendment

#### Description

The Roanoke Shores Homeowners Association has submitted a zoning text amendment request to revise the RS-8 district to include non-conforming language specific to the Roanoke Shores apartment complex located at 117 Old NC 345 on Roanoke Island. A staff report explaining the details of the request is included with this cover sheet.

#### **Board Action Requested**

Motion to schedule a public hearing: I move that a public hearing on the proposed RS-8 amendment be scheduled for 5:30 p.m. on May 21, 2018."

#### **Item Presenter**

Donna Creef, Planning Director

#### STAFF REPORT - May 7, 2018 DCBC MEETING

- FROM: Donna Creef, Planning Director
- RE: Roanoke Shores Homeowners Association Text Amendment to RS-8 District

The Roanoke Shores Homeowners Association has submitted a text amendment application to amend the RS-8 district regulations to add non-conforming language specific to their property. Roanoke Shores is a multifamily structure located at 117 Old NC 345 on the north end of Roanoke Island. It was constructed in 1985 and features 21 units. All of the units are currently individually owned. When the structure was constructed in 1985, the units were owned by one entity and rented by the entity.

The RS-8 district is one of the original zoning districts on Roanoke Island and when zoning regulations were first adopted in 1975. At that time, the RS-8 dwelling density was eight units per acre. In 2003, Dare County adopted comprehensive revisions to all multifamily zoning districts to decrease the dwelling densities in each district. Currently, the dwelling density in the RS-8 district is six units per acre. The Roanoke Shores property is 2.5 acres in size. Based on the current dwelling density, only 15 units could be rebuilt if the structure was damaged beyond 50% of its value based on the non-conforming language found in Section 22-49 of the Dare County Zoning Ordinance. Section 22-49 states that any non-conforming structure damaged beyond 50% of its value must be rebuilt in conformance with the current regulations.

Recently, the manager of the RSHOA met with me to discuss the property and the issue of the structure being non-conforming with the RS-8 dwelling density was identified. It was my recommendation that the RSHOA seek an amendment to the RS-8 district regulations to add specific language to the RS-8 district that would allow all of the units to be rebuilt if it was damaged more than 50% of its value. With the units being individually owned and the current dwelling density permitting only six units per acre, it would be a quagmire to decide how to ownership of twenty-one units if the property was substantially damaged.

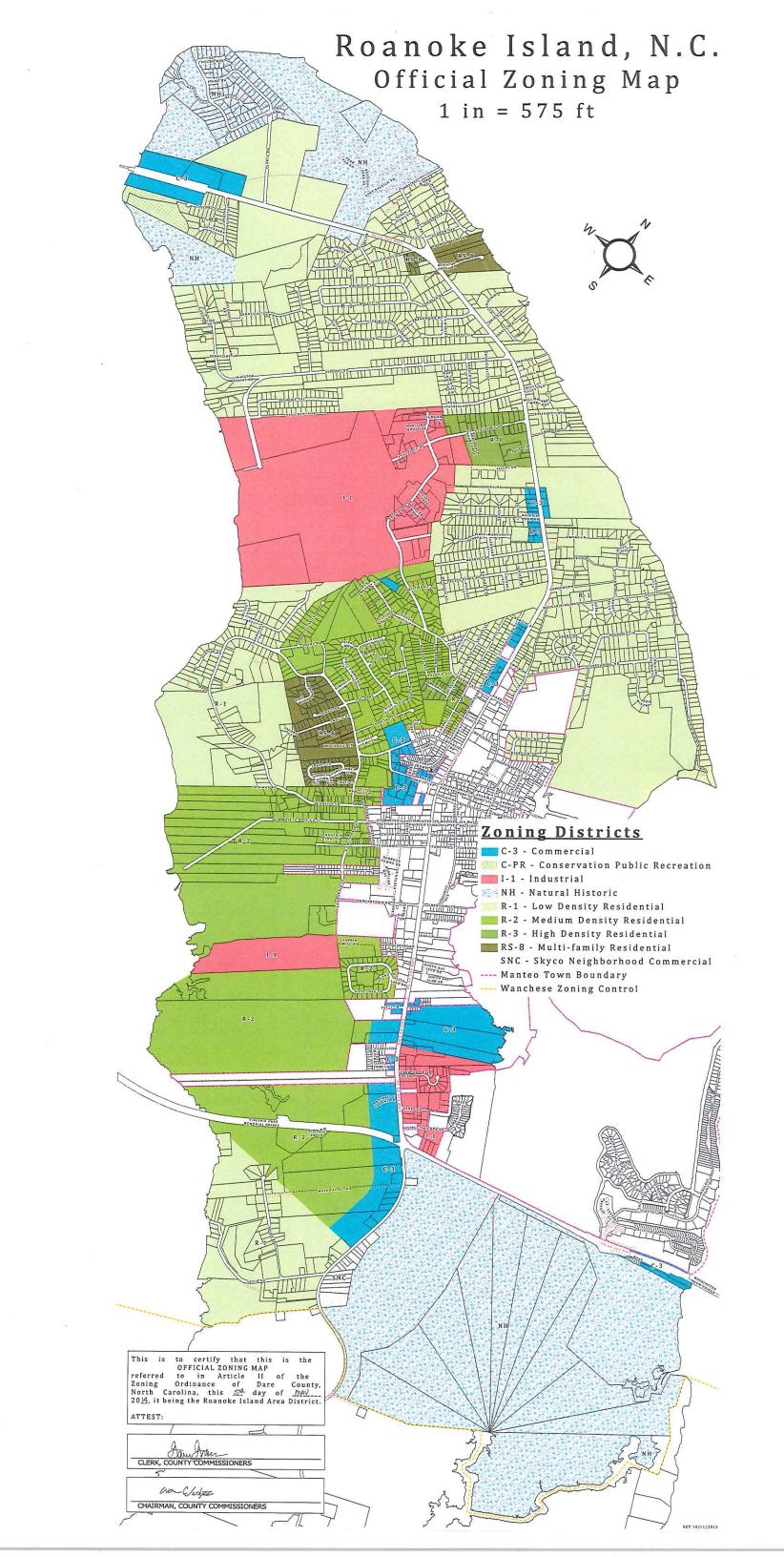
#### Proposed non-conforming language for RS-8 district:

RS-8 (e) Non-conforming Multifamily Structures -- If any non-conforming multifamily structure constructed before 2003 when the RS-8 dwelling density was decreased to six units per acre is destroyed or damaged more than 50% of its market value, the structure may be reconstructed to its former dwelling density at the time of its original construction but no greater.

The Planning Board reviewed this proposal at their April 9, 2018 meeting and voted unanimously to recommend approval of the proposed amendment. The consistency statement from the Planning Board is attached with my staff report.

In order for the Board of Commissioners to move forward with the RSHOA amendment, a public hearing must be held on the matter. The first available date for such as hearing is May 21, 2018 at 5:30 pm.

Motion to schedule a hearing: "I move that a public hearing on the proposed RS-8 amendment be scheduled for 5:30 pm on May 21, 2018."





J.D. Johnson Realty -- Wanchese Zoning Map Amendment

#### Description

Mr. J. D. Johnson has filed a zoning map amendment request to reclassify lots 2-4 of the George Mann Subdivision from its current classification of Baumtown Traditional (BT) to Highway 345 business. The property is located on Highway 345 near the intersection of Baumtown Road. A detailed staff report is attached. The requested action is to schedule a public hearing on this request for May 21, 2018.

#### **Board Action Requested**

Motion to schedule hearing: "I move that a public hearing on the Johnson rezoning request be scheduled for May 21, 2018 at 5:30 p.m."

#### **Item Presenter**

Donna Creef, Planning Director

#### STAFF REPORT

DATE: May 7, 2018 DCBC MEETING

FROM: Donna Creef, Planning Director

RE: J. D. Johnson Realty – Wanchese Zoning Map Amendment

Mr. J. D. Johnson has filed a zoning map amendment request to rezone lots 2, 3 and 4 of the George Mann Tract on Roanoke Island. All of the property has frontage on Highway 345 and is currently classified as Baumtown Traditional on the Wanchese zoning map. Mr. Johnson is seeking to rezone the property to Highway 345 Business. A copy of the aerial tax map of the three parcels is attached. The property is contiguous with land zoned Highway 345 to the north, land zoned Baumtown Traditional to the east, and Highway 345 across the road.

I have also attached a copy of both the BT district and the H345 district for the Board members to read in context the intent statements and the scope of uses allowed in each district. The BT intent statement references the desire to preserve the traditional family-fishing village lifestyle through commercial accessory uses located in conjunction with a principal residential use. The purpose of the district is to allow for the continuation of goods and services associated with a coastal village location that furnishes a broad range of services and commodities to meet the needs of local residents, the entire community, and seasonal visitors while retaining the charm of a fishing village. The uses permitted in the BT district include residential dwellings, traditional village business (commercial accessory with principal residential), nursery and greenhouse, churches, animal rehabilitation centers and fishing and hunting clubs.

The intent statement for the H345 district provides for a mix of residential and commercial neighborhoods offering a broad range of services and commodities to serve the seasonal and local residents. The list of allowed uses includes many commercial uses such as hotels, boat yards, offices, dwellings, boat building, travel trailer parks, marinas, and food service. The H345 is commercial district with a much larger scope of potential uses than offered in the BT district.

The Highway 345 Business district applies to numerous properties on both sides of Highway 345 as you enter Wanchese village. The Baumtown Traditional district applies along Baumtown Road and to a handful of property that front Highway 345 including the Johnson property. The existing land uses along Highway 345 include a dentist office, the Dare Challenge facility, a warehouse facility, a radio tower and a campground. There is a farm market currently under construction on Lot 1 of the George Man Tract. This parcel is not part of the rezoning request and is zoned Baumtown Traditional. The individual leasing lot 1 has farm identification number which exempts the property from county zoning restrictions. The owner of lot 1 and the owner of the large parcel to the east of the site expressed opposition to the rezoning during the Planning Board review. The Planning Board held a public hearing on the rezoning application at their April 9 meeting. Following the hearing, the Planning Board voted unanimously to recommend approval of the request. During the discussion, the Planning Board members acknowledged the opposition of the adjoining owners but stated the location of the property along Highway 345 and the surrounding commercial uses were factors contributing to the favorable recommendation.

Should it be the consensus of the Board to offer additional consideration of the Johnson rezoning, a public hearing on the matter must be held. The requested action today is the scheduling of a public hearing on May 21, 2018.

Motion to schedule a hearing: "I move that a public hearing be scheduled on the Johnson rezoning for May 21, 2018 at 5:30 p.m."

If it is the consensus of the Board to not offer any additional consideration to this request, then no further action is needed.

## **Zoning Amendment Petition Application**



A. APPLICANT INFORMATION

NAME: Unathan D. Johnson TELEPHONE: 252-305-9982
ADDRESS: LOT 2, 3,4 George Mann COMMUNITY: Wonchese
Tract 2
(P.O. Box 340 - Manteo, NC 27954)
B. PRESENT ZONING CLASSIFICATION: $\mathcal{BT}$
C. REQUESTED ZONING CHANGE: <u>H345</u>
D. EXPLANATION OF REQUEST: Map Amendment from BT to H345
Higher intensity of uses - all uses associated w/H345
would be permitted including wholesale Hunting/Fishing
supplies

E. ATTACHED IS THE FOLLOWING DATA AS REQUESTED:

- **♦ 12 COPIES OF THE PLAT OR SURVEY OF PROPERTY TO BE CONSIDERED.**
- ♦ CHECK IN THE AMOUNT OF FOUR HUNDRED \$400.00 MADE PAYABLE TO THE DARE COUNTY PLANNING DEPARTMENT. WE UNDERSTAND THAT ADVERTISING COST MAY BE FORWARDED TO US AT A LATER DATE.
- ✤ A LIST OF NAMES AND ADDRESSES OF ADJOINING PROPERTY OWNERS VERIFIED BY PIN# AS LISTED ON THE DARE COUNTY TAX RECORDS.

We, I, <u>Jona than</u> <u>D</u> <u>bhn son</u> understand that Section 22.83 and Section 22.84 require a fee of four hundred (\$400.00), plus the cost of the required legal advertisement, to be paid to the County with the application to cover the costs of advertising and other administrative expenses involved.

2-19-18

Date of application

Name of applicant (signature in full)

Isnathon D Johnson **Printed Name of applicant** 

Rev. 7-15



This map is prepared from data used for the inventory of	0 Nc 345 Wanchese, NC 27981	Tax Ownership Current Tax Value		Map Legend	
data used for the inventory of the real property for tax purposes. Primary information sources such as recorded deeds, plass, wills, and other primary public records should be consulted for verification of the information contained in this map. DARE COUNTY ASSUMES NO LEGAL RESPONSIBILITY FOR THE INFORMATION CONTAINED IN THIS MAP.	Wanchese, NC 27981Parcel: 028158004Pin: 979800336315Tax District: WancheseSubdivision: George Mann Tract 2Lot-Blk-Sect: Lot: 4 Blk: Sec:Property Use: Vacant Land (Private)Building Type:Year Built:	J.d. Johnson Realty & Construction Llc	Land33,300Building0Misc0Total33,300	Scale: 1:4,265 Basemap: Aerials(2012) Parcel Lines Property Line Selected Parcel	
Print Date: Feb 19, 2018					





Tax District: Wanchese Subdivision: George Mann Tract 2 Lot-Blk-Sect: Lot: 2 Blk: Sec: Property Use: Vacant Land (Private) **Building Type:** Year Built:

Distances Measured to nearest Residences

Total

36,400

- Property Line

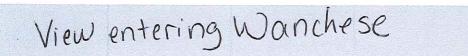
Selected Parcel

36

ASSUMES NO LEGAL RESPONSIBILITY FOR THE INFORMATION CONTAINED IN THIS MAP.

DARE COUNTY

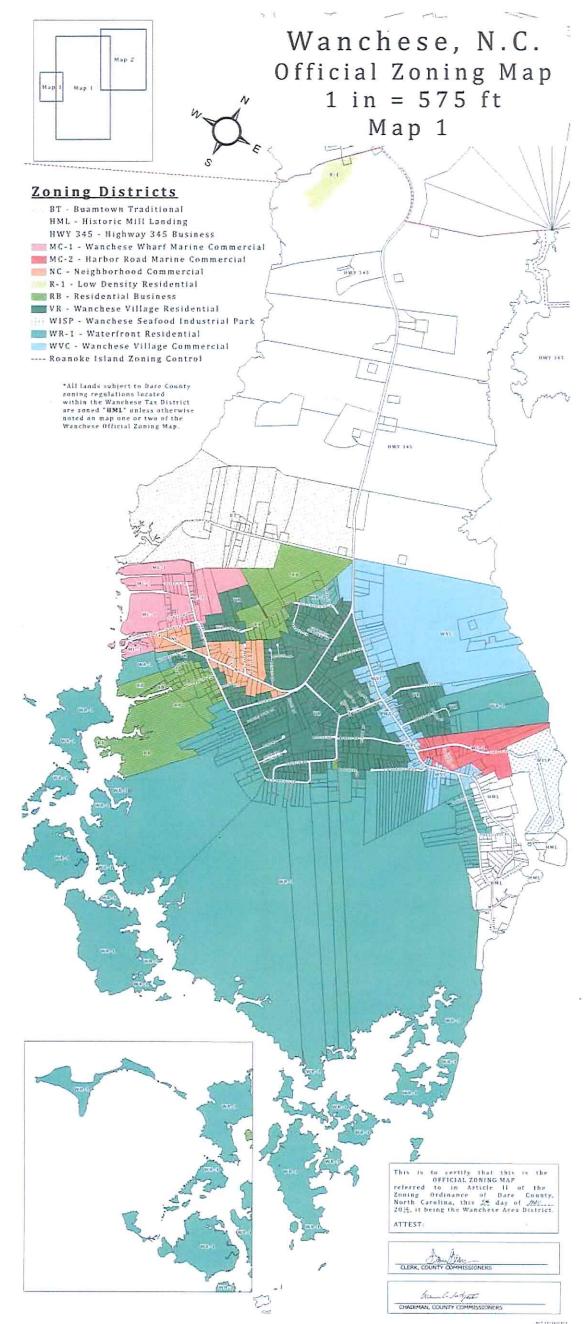
Print Date: Apr 6, 201 8



# Location of Proposed







#### SECTION 22-27.9 - BAUMTOWN TRADITIONAL ZONING DISTRICT (BT)

Baumtown Road.

(a) Scope and intent: The Baumtown Traditional Zoning District is bound on the north and south by Baumtown Road, and a portion of the lands that lie along Highway 345 at Baumtown Road. The district is established to recognize and preserve the traditional family-fishing village lifestyle, whereby a property owner or family member conducts water-related or non-water related commercial accessory business on a lot or parcel in conjunction with the principal residential use. Moreover, the district provides space for diverse types of agricultural farming and related activities in a quiet area with low vehicular traffic flow. Furthermore, the district is designed to promote and accommodate such future development that is sensitive to any environmental conditions in close proximity of the Dare County well field sites. Land uses in the district provide for a compatible, harmonious and orderly business relationship as a way of life, which gives the village its attractiveness, both as a place to live and a place to visit.

The purpose of this district is to allow for the continuation of goods and services associated with a coastal village location that furnishes a broad range of services and commodities to meet the needs of the local residents, the entire community, and seasonal visitors while retaining the charm of a quaint fishing village.

(b) Permitted uses: Any use in existence on March 24, 2006 shall be allowed to continue in operation without seeking approval from Dare County, regardless if that use is listed as a permitted use or is listed as a conditional use in any of the Wanchese zoning districts. Additions or expansions of uses in existence on March 24, 2006 shall be subject to administrative review and approval by the Dare County Planning Department for compliance with the zoning regulations. Construction of additional principal use structures at existing business sites that would require a conditional use permit if not already established prior to March 24, 2006 shall trigger review and approval under the conditional use permit process.

The following uses shall be permitted by right and any use not permitted herein shall be deemed prohibited:

(1) Detached single-family dwellings on individual lots.

(2) Single-family mobile homes located on individual lots, provided

a. Compliance with building code for mobile homes in a hurricane area.

**b.** Compliance with the requirements of the building inspector regarding skirting materials and skirting area.

(3) Bed and breakfast homes.

- a. Small bed and breakfast home as defined in Section 22-2.
- b. Large bed and breakfast home as defined in Section 22-2.

(4) Small child care home as defined in Section 22-2.

(5) Customary accessory uses associated with principal use, including windmills not to exceed height limit of this district, garages, sheds, swimming pools, tennis courts, commercial accessory business structures and any other structure associated with a residential use.

(6) Accessory dwelling unit associated with principal residential use and referred to as a "guesthouse" is permitted, subject to compliance with all supplementary local, state and federal permit approvals and in addition to the following:

**a.** An accessory dwelling unit may be attached to the principal residence or be detached from the principal residence. The size of an accessory dwelling unit, whether attached to or detached from, the principal residence shall not exceed 900 square feet of heated space.

**b.** An accessory dwelling unit, whether attached to or detached from the principal residence, shall be located on the site in conformance with the building setbacks of this zoning district.

**c.** The owner of the property and/or family member shall occupy either the primary residence or accessory dwelling unit.

d. One additional off-street parking space shall be required.

**e.** An accessory dwelling unit shall not be subdivided or segregated in ownership from the principal use structure.

f. An outbuilding on a residential lot that exists at the time of adoption of this ordinance may be converted into an accessory dwelling unit, if lot coverage can be met for the accessory unit and the primary residence.

**g.** The accessory dwelling unit shall be constructed according to all applicable state and federal regulations and local building code requirements, including federal floodplain elevation regulations if applicable.

**h.** Once permitted, the property owner shall submit annual verification of year round occupancy of the principal use structure or the accessory dwelling unit to the Dare County Planning Department, if necessary.

i. Travel trailers, recreational vehicles, and/or mobile homes shall not be used as accessory dwelling units.

j. Accessory dwelling units shall not be used for any commercial or business activity.

(7) Traditional village business – A commercial accessory use conducted by owner and/or family member residing on the lot or parcel of the principal residence provided the following conditions are met:

a. Property owner and/or family member operates a business and resides on the premises.

**b.** Merchandise produced on or off of the premises may be sold on premises.

c. An accessory commercial building shall not exceed 1,200 square feet. In addition, 25% of the total floor area of the principal residence may be used for said business.

**d.** One indirectly lighted freestanding sign, not to exceed 36 square feet, may be posted on the property.

e. On-site parking for up to 4 spaces shall be provided on the site.

f. Visual buffer: A 6-foot opaque wooden fence or vegetative buffer shall be provided for any business established after March 24, 2006. In some instances, existing dense shrubs, trees, and plants may provide screening.

**g.** In the case where a property owner owns land that is contiguous to the principal residential use and accessory business, said land may be used as an extension and a part of the traditional village business use.

**h.** The traditional village business shall be located a minimum of 15 feet from any front property line and a minimum of 10 feet from any side or rear property line. The setbacks listed in subsection (d) of this district shall not apply.

i. An average of 3 non-resident employees may be employed.

The following list of uses may be permitted as a traditional village business including, but not limited to:

- (1) Offices: business, financial, professional, and medical.
- (2) Retail/wholesale shops:
  - a. Antiques, furniture, and home decor.
  - b. Apparel.
  - c. Artist and art supplies.
  - d. Bait and tackle supplies.
  - e. Beehives.
  - f. Books.
  - g. Camera and photo supplies.
  - h. Coffee/tea cakes, pies, bakery goods and edibles.
  - i. Florist.
  - j. Fruit and vegetable stand.
  - k. Gifts and imports.
  - **I.** Hobby goods.
  - m. Hunting and fishing supplies.
  - n. Jewelry.
  - o. Leather goods.
  - p. Millinery shop.
  - q. Music shop.
  - r. Photography equipment sales and service.
  - s. Sewing shop/needle works, dry goods and supplies.
  - t. Tack and equestrian associated sales.
  - u. Toys.
  - v. Upholstery.
  - w. Woodcarving, ducks and other wildlife.
- (3) Service establishments:
  - a. Automobile detailing.
  - **b.** Barber and beauty shops including tanning and exercise facilities.

- c. Bicycle rentals with buffered storage area.
- d. Boarding of horses, equestrian associated activities according to state regulations.
- e. Boat building shop (not to exceed 1,200 sq. ft. boat size limited to 36 ft.).
- f. Bricklayer.
- g. Bake shops cakes, pastries, edibles and bakery goods.
- h. Carpenter/cabinet/woodworking.
- i. Catering business.
- j. Computer and internet services.
- k. Concrete finishing business and equipment.
- 1. Crab pot storage and other crabbing and commercial fishing gear.
- m. Crab shedders and associated operations.
- n. Craft production and retail sales.
- o. Electrician.
- p. Electronics.
- q. Excavating and equipment.
- r. Hardwood flooring, carpet, vinyl and ceramic tile installation.
- s. Heating and air.
- t. Historic home place tours and interpretation of village lifestyle.
- u. Home schooling.
- v. House and boat moving business.
- w. Landscape and lawn care.
- x. Music lessons.
- y. Outboard engine repair.
- z. Painter and dry wall.
- aa. Photographer.
- bb. Plumber.
- cc. Potter, clay works, ceramics.
- dd. Pressure washing business.
- ee. Radio, TV broadcasting and film production studio.
- ff. Roofer.
- gg. Seafood sales as per North Carolina regulations.
- hh. Siding contractors.
- ii. Small engine repair.

jj. Small trucking business – parking business truck on site.

kk. Taxidermist.

II. Tree removal, stump grinding, log splitting and wood sales.

mm. Welding shop.

(4) Specific waterfront commercial accessory uses associated with principal use:

a. Commercial fishing and crabbing business, retail and wholesale markets, including all rigging and storage of crab and fish gear.

**b.** Boat dockage of 10 slips or less.

c. Boat shop not to exceed 1,200 square feet of floor area and limited to the construction of 36-foot boats.

d. Boathouses and sheds.

e. Boat rentals limited to non-motorized watercraft.

f. Fishing party excursions 1/2 day and full day trips.

g. Private boat ramps for residential use or commercial accessory use.

h. Schools offering private lessons for sailing and other outdoor activities.

(8) Agriculture farming, livestock, waterfowl, poultry and related activities for personal use.

(9) Aquaculture and associated activities related to fish farming as regulated by the State of North Carolina.

(10) Nursery/greenhouse/tree/shrub farms and associated activities with buffered storage areas.

(11) Private home antennas and on-site accessory business use antennas.

(12) County owned and leased facilities

(13) Heritage gardens – Designated areas of land leased to the public for gardening projects.

(c) Conditional uses: Any use in existence on March 24, 2006 shall be allowed to continue in operation without seeking approval from Dare County, regardless if that use is listed as a permitted use or is listed as a conditional use in any of the Wanchese zoning districts. Additions or expansions of uses in existence on March 24, 2006 shall be subject to administrative review and approval by the Dare County Planning Department for compliance with the zoning regulations. Construction of additional principal use structures at existing business sites that would require a conditional use permit if not already established prior to March 24, 2006 shall trigger review and approval under the conditional use permit process.

The following conditional uses and no other conditional uses may be permitted, subject to the requirements of this district and the regulations and requirements imposed by the Board of Commissioners as provided by Article IX of this chapter. Any use not permitted herein shall be deemed prohibited.

(1) Churches, cemeteries, schools and other public buildings.

(2) Animal rehabilitation home center (required permits from North Carolina Wildlife Resources).

(3) Elder in-home care, up to 4 non-related patients (private home nursing) provided the following minimum requirements are met:

**a.** Employee and visitor parking according to Section 22-56 in addition to 1 parking space for each non-resident employee.

b. Other reasonable conditions imposed by the Board of Commissioners.

(4) Fishing and hunting club, horse ranch including amenities such as clubhouse facility with overnight lodging or guest quarters, swimming pools, storage buildings, piers docks, private beach and boat launching subject to other requirements of the chapter including Section 22-31 as may be applicable and provided the following minimum requirements are met:

a. Overnight guest facilities - see density requirements for hotels, motels, and seasonal lodging.

**b.** Number of rooms in lodging facility – see density requirements for hotel, motel, and seasonal lodging.

c. Individual guest quarters – as calculated for group housing development projects.

d. Prohibit mooring or permanent floating homes and other permanent floating structures as defined in 15A NCAC 7M00602 in the surrounding public trust waters of Dare County.

e. Other reasonable conditions that may be imposed by the Board of Commissioners.

(5) Pet grooming provided the following minimum requirements are met:

a. Shall be owner and/or family occupied residential premises.

**b.** Day care only for grooming - hours of operation limited to 7:00 a.m. to 6:00 p.m.

c. No outdoor run facilities and no overnight occupancy (not a kennel).

d. Other reasonable conditions imposed by the Board of Commissioners.

(6) Private and public utilities (shall provide vegetative buffer at least 10 feet in height).

(7) Small childcare center, large childcare center - As defined in Sec. 22.2 and only associated with a church, school or other public building.

(8) Spoil sites for maintenance dredging.

#### (d) Dimensional requirements for all residential uses:

(1) Minimum lot size:

**a.** Single-family lots with accessory dwelling units and accessory commercial structures used in association with a single–family use shall be of sufficient size to meet the requirements of the Dare County Environmental Health Department and to provide adequate setbacks for the single-family structure, accessory dwelling unit and all other accessory use structures.

Existing lots – All lots that were subdivided and recorded before March 24, 2006 shall meet the approval of the Dare County Environmental Health Department for well and on-site wastewater systems. The setbacks and lot coverage standards of Section 22-27.18 shall apply to lots recorded before March 24, 2006.

b. Newly platted lots -- For those lots subdivided and recorded after March 24, 2006:

Single family lots:

15,000 square feet of soils not classified as coastal wetlands for lots connected to a central water supply.

20,000 square feet of soils not classified as coastal wetlands for lots connected to a private well.

- (2) Minimum lot width: 75 feet at building setback line.
- (3) Minimum front yard: 25 feet.

(4) Minimum side yard: 10 feet; an additional 5-foot side setback for corner lots adjacent to a street. Lots less than 75 feet in width shall have an 8-foot setback and an additional 5-foot setback for corner lots adjacent to a street.

(5) Minimum rear yard: 20 feet maximum, or 20% of lot depth. Zero line setback for waterfront lots.

(6) Lot coverage: 30% as defined in Section 22-2. Lot coverage of 50% may be authorized for those sites with an accessory dwelling unit and/or a traditional village business.

(7) Building height: 40 feet to the highest elevation of any feature of the structure or portion of the roof measured from the base flood elevation, from natural ground elevation if natural ground elevation exceeds the base flood elevation, or from an unnatural ground elevation created by placement of fill material on a site on or before March 24, 2006. Chimneys, lightning rods, weather vanes, wind gauges, and other similar roof appurtenances shall not be considered the highest portion of the roof. The pitch of the principal roof shall be no less than 4/12. Principal roof is defined as the largest section of the roof on the structure.

## (e) Dimensional requirements for individual commercial use on separate lot or parcel that is not in conjunction with the principal residential use:

(1) Minimum lot size: Commercial lots need to be of sufficient size to meet the requirements of the Dare County Environmental Health Department and to provide adequate siting for structures, parking, loading and maneuvering space according to Section 22-56. Also, a visual buffer of vegetation or fencing and a 20-foot wide setback is required when an individual commercial use abuts a residential use or residential zone. All outdoor lighting shall be low profile, shielded, with glare directed on site and away from all adjoining properties and streets.

(2) Minimum front yard: 15 feet.

(3) Minimum side yard: 10 feet; an additional 5-foot side setback for corner lots adjacent to a street. Lots less than 75 feet in width shall have an 8-foot setback and an additional 5-foot setback for corner lots adjacent to a street.

(4) Minimum rear yard: 20 feet maximum, or 20% of lot depth for interior lots. Zero line setback for waterfront lots.

(5) Lot coverage: 60% as defined in Section 22-2.

(6) Building height: 40 feet to the highest elevation of any feature of the structure or portion of the roof measured from the base flood elevation, from natural ground elevation if natural ground elevation exceeds the base flood elevation, or from an unnatural ground elevation created by placement of fill material on a site on or before March 24 2006. Chimneys, lightning rods, weather vanes, wind gauges, and other similar roof appurtenances shall not be considered the highest portion of the roof. The pitch of the principal roof shall be no less than 4/12. Principal roof is defined as the largest section of the roof on the structure.

(7) Maximum commercial building size: 10,000 square feet excluding decks, porches, and other nonheated space. Churches, fire stations, public buildings and schools are excluded from this building size limitation.

(8) Density limitations for motels, hotels, and similar seasonal lodging structures:

**a.** Structures on a lot or tract that has no soils classified as wetlands, coastal marsh or section 404 jurisdictional soils: 10 rental rooms per acre.

**b.** Structures on a lot or tract that has between .01% and 19.9% of its soils classified as wetlands, coastal marsh, or section 404 jurisdictional soils: 8 rental rooms per acre.

c. Structures on a lot or tract that has more than 20% of its soils classified as wetlands, coastal marsh or section 404 jurisdictional soils: 6 rental rooms per acre.

(f) Non-conforming uses and non-conforming structures: The standards of Section 22-27.19 shall apply to this district.

(g) Performance standards and other information: The standards of Section 22-27.20 shall apply to this district.

(h) The sections contained in Article I, Article III, Article VII, Article VIII, and Article IX of the Dare County Zoning Ordinance shall apply to this district.

(Adopted by the DCBC on March 24, 2006; Amended 2-20-2017)

### SECTION 22-27.16-HIGHWAY 345 BUSINESS DISTRICT (HWY 345)

The Highway 345 Business district shown on the Dare County tax map, tax district 17 originally dated November 20, 1975 depicts tracts of land that lie along Highway NC 345 bounded on the east by the Pamlico Sound and on the west by Croatan Sound and Oyster Creek. Moreover, these tracts of land border NC Highway 345, a heavily traveled thoroughfare to the southern portion of Roanoke Island.

(a) Scope and intent: This district provides for a mix of residential and commercial neighborhoods that offer a broad range of services and commodities that will serve seasonal and local residents. The mixed residential district includes single family homes and duplex homes in a group housing development setting that support private wells or a central water supply with alternative methods of wastewater treatment facilities approved by the Dare County Environmental Health Department (not to include centralized urban-style wastewater collection and treatment systems). A maximum gross building size of 30,000 square feet (10,000 square feet of heated space and 20,000 square feet of non-heated space) for commercial structures is included in the regulations thereby allowing for future compatible land uses such as hotels and motels and similar lodging structures.

Furthermore, the Highway 345 Business District provides for land uses that allow goods and services for people and industry while strengthening the economic base of Dare County and ensures the protection of the fragile and pleasant atmosphere at the south end of Roanoke Island. Highway 345 provides the only vehicular transportation route into the Village of Wanchese. There is concern for the large expanses of wetland areas along NC 345 that contain marginal soils and are not suitable for high-density development. A number of water supply wells, which serve the Dare County water system, are located within this district. Land use adjacent to these wells is also a concern and is reflected in the minimum lot size established in this zoning district. Density in this district shall be limited to 20,000 square feet and duplex lots limited to 25,000 square feet. Another goal is to protect the quality of the communities' surface water and ground water supply particularly with the close proximity of this district to Broad Creek, Croatan Sound, Pamlico Sound and the various creeks and canals that serve as nursery areas for fish and wildlife.

(b) Permitted uses: Any use in existence on June 5, 2006 shall be allowed to continue in operation without seeking approval from Dare County, regardless if that use is listed as a permitted use or is listed as a conditional use in any of the Wanchese zoning districts. Additions or expansion of uses in existence on June 5, 2006 shall be subject to administrative review and approval by the Dare County Planning Department for compliance with the zoning regulations. Construction of additional principal use structures at existing business sites that would require a conditional use permit if not already established prior to June 5, 2006 shall trigger review and approval under the conditional use permit process.

The following uses and no other uses shall be permitted by right. Any use not permitted herein shall be deemed prohibited.

(1) Commercial uses:

- a. Boat yards and repair.
- b. Boat and motor display, sales and service.
- c. Boarding of horses, equestrian related uses and activities, tack shop.
- d. Box making facilities.
- e. Cabinet and woodworking shop.
- f. Contractors' offices, supplies and services.
- g. Crab shedding operations and associated equipment.
- h. Commercial fishing nets, sales, service and storage.
- i. Crab pot storage and other crabbing and commercial fishing gear.
- j. Docks private, public and commercial.
- k. Dry cleaning and laundromats.
- 1. Electrical equipment, sales and service.
- m. Electronic equipment, sales and service.
- n. General village store without fuel pumps and not associated with a marina.

**o.** Hotels, motels – administrative review for one principal building per site, two or more buildings require conditional use permit for group development –see CUP.

**p.** Fish houses, including packing, processing, seafood sales, storage and loading and unloading trawlers.

- q. Fishing party fishing excursions and associated services.
- r. Food services -carryout (if seating see CUP).
- s. Hardware supplies.
- t. Heating and air, sales, service.
- u. Tourist homes as defined in Section 22-2.
- v. Mobile home parks according to the Mobile Home Park Ordinance.
- w. Plumbing supplies, sales and service.
- x. Retail shops, including, but not limited to gifts and imports.
- y. Radio, TV broadcasting and film production studio.
- z. Seafood processing and seafood market sales wholesale /retail.
- aa. Schools, commercial limited to sailing/marine oriented outdoor lifestyle.
- bb. Travel trailer parks and campgrounds according to the Travel Trailer Park Ordinance.
- cc. Upholstery, fabric dry goods.
- dd. Village general store without fuel pumps and not associated with a marina.
- ee. Welding shop and steel fabrication.

(2) Single-family dwelling in conjunction with a commercial business may be located above or in the rear of a commercial building, or a detached structure, provided that all federal, state and local regulations are met. Additional parking for the residential use shall not be needed.

(3) Detached single-family dwelling on individual lots or parcels.

(4) Bed and breakfast homes.

a. Small bed and breakfast home as defined in Section 22-2.

**b.** Large bed and breakfast home as defined in Section 22-2.

(5) Single-family mobile homes on individual lots, provided that:

a. Compliance with the building code for mobile homes in a hurricane area.

**b.** Compliance with the building inspector requirements regarding skirting material and skirting area.

(6) Duplexes.

(7) Small childcare homes as defined in Section 22-2.

(8) Customary accessory uses associated with commercial or residential principal use, including windmills, not to exceed height limit of this district, garages, sheds, swimming pools and other accessory uses associated with the commercial and or residential use.

(9) Accessory dwelling unit associated with residential use referred to as a "guesthouse" is permitted, subject to the following requirements:

**a.** A dwelling unit may be attached to the principal residence or may be detached from the principal residence. The size of the accessory dwelling unit, whether attached to or detached from principal residence, shall not to exceed 900 square feet of heated space.

**b.** An accessory dwelling unit, whether attached to or detached from the principal residence, shall be located on the lot in conformance with the building setbacks of this zoning district.

**c.** Owner and/or family members shall occupy either the primary residence or accessory dwelling unit.

d. One additional off-street parking space shall be required.

e. Accessory dwelling unit shall not be subdivided or otherwise segregated in ownership from the primary residence.

**f.** An outbuilding on a residential lot that exists at the time of adoption of this ordinance may be converted into an accessory building unit, provided that lot overage is met for the dwelling unit and the primary residence.

**g.** The accessory dwelling unit shall be constructed according to all applicable federal, state regulations and local building inspection requirements. And, if applicable, compliance with federal flood plain elevation standards.

**h.** Once permitted, the property owner shall submit annual verification of year round occupancy of the principal structure or the accessory dwelling unit to the Dare County Zoning Administrator, if necessary.

i. Travel trailers, recreational vehicles, and/or mobile homes shall not be used as accessory dwelling units.

j. Accessory dwelling units shall not be used for any commercial or business use.

(10) Traditional village business – A commercial accessory use conducted by owner and/or family member residing on the lot or parcel of the principal residence provided the following conditions are met:

a. Property owner and/or family member operates a business and resides on the premises.

b. Merchandise produced on or off of the premises may be sold on premises.

c. An accessory commercial building shall not exceed 1,200 square feet. In addition, 25% of the total floor area of the principal residence may be used for said business.

d. One indirectly lighted freestanding sign, not to exceed 36 square feet, may be posted on the property.

e. On-site parking for up to 4 spaces shall be provided on the site.

**f.** Visual buffer: A 6-foot opaque wooden fence or vegetative buffer shall be provided for any business established after June 5, 2006. In some instances, existing dense shrubs, trees, and plants may provide screening.

g. In the case where a property owner owns land that is contiguous to the principal residential use and accessory business, said land may be used as an extension and a part of the traditional village business use. The setbacks listed in subsection (d) of this district shall not apply.

**h.** The traditional village business shall be located a minimum of 15 feet from the front property line and 10 feet from any side or rear property line. The setbacks listed in subsection (d) of this district shall not apply.

i. An average of 3 non-resident employees may be employed.

The following list of uses may be permitted as a traditional village business including, but not limited to:

- 1. Offices: business, financial, professional, and medical.
- 2. Retail/wholesale shops:
  - a. Antiques, furniture, and home decor.
  - b. Apparel.
  - c. Artist and art supplies.
  - d. Bait and tackle supplies.
  - e. Beehives.
  - f. Books.
  - g. Camera and photo supplies.
  - h. Coffee/tea cakes, pies, bakery goods and edibles.
  - i. Florist.
  - j. Fruit and vegetable stand.
  - k. Gifts and imports.
  - I. Hobby goods.
  - m. Hunting and fishing supplies.
  - **n.** Jewelry.

- o. Leather goods.
- p. Millinery shop.
- q. Music shop.
- r. Photography equipment sales and service.
- s. Sewing shop/needle works, dry goods and supplies.
- t. Tack and equestrian associated sales.
- u. Toys.
- v. Upholstery.
- w. Woodcarving, ducks and other wildlife.
- 3. Service establishments:
  - a. Automobile detailing.
  - b. Barber and beauty shops including tanning and exercise facilities.
  - c. Bicycle rentals with buffered storage area.
  - d. Boarding of horses, equestrian associated activities according to state regulations.
  - e. Boat building shop (not to exceed 1,200 sq. ft. boat size limited to 36 ft.).
  - f. Bricklayer.
  - g. Bake shops cakes, pastries, edibles and bakery goods.
  - h. Carpenter/cabinet/wood- working.
  - i. Catering business.
  - j. Computer and internet services.
  - k. Concrete finishing business and equipment.
  - 1. Crab pot storage and other crabbing and commercial fishing gear.
  - m. Crab shedders and associated operations.
  - n. Craft production and retail sales.
  - o. Electrician.
  - p. Electronics.
  - q. Excavating and equipment.
  - r. Hardwood flooring, carpet, vinyl and ceramic tile installation.
  - s. Heating and air.
  - t. History home place tours and interpretation of village lifestyle.
  - u. Home schooling.
  - v. House and boat moving business.
  - w. Landscape and lawn care.

- x. Music lessons.
- y. Outboard engine repair.
- z. Painter and dry wall.
- aa. Photographer.
- bb. Plumber.
- cc. Potter, clay works, ceramics.
- dd. Pressure washing business.
- ee. Radio, TV broadcasting and film production studio.
- ff. Roofer.
- gg. Seafood sales as per North Carolina regulations.
- hh. Small engine repair.
- ii. Small trucking business parking business truck on site.
- jj. Taxidermist.
- kk. Tree removal, stump grinding, log splitting and wood sales.
- II. Welding shop.
- 4. Specific waterfront commercial accessory uses associated with principal use:

**a.** Commercial fishing and crabbing business, retail and wholesale markets, including all rigging and storage of crab and fish gear.

**b.** Boat dockage of 10 slips or less.

**c.** Boat shop not to exceed 1200 square feet of floor area and limited to the construction of 36-foot boats.

- d. Boathouses and sheds.
- e. Boat rentals limited to non-motorized watercraft.
- f. Fishing party excursions 1/2 day and full day trips.
- g. Private boat ramps for residential use or commercial accessory use.
- h. Schools offering private lessons for sailing and other outdoor activities.
- (11) Agriculture farming, livestock, waterfowl, poultry and related activities for personal use.
- (12) Aquaculture and associated activities related to fish farming as regulated by the State.
- (13) Private home antennas and on-site accessory business use antennas.
- (14) County, state and U.S. government owned and leased facilities.
- (15) Heritage gardens designated areas of land leased to the public for gardening projects.

(16) Radio and broadcast studio facilities and associated broadcast transmission towers that existed prior to March 24, 2006. Replacement or reconstruction of towers that existed prior to March 24, 2006 may be authorized as permitted uses provided that such towers have received all necessary Federal Communications Commission license and Federal Aviation Administration license prior to March 24, 2006

and shall not exceed the height authorized by the FCC. The standards of Section 22-29.2 shall not apply to towers that qualify for replacement under this section. Replacement towers shall be located in a manner that maximizes separations from all property lines and in no case shall the setbacks be less than those of the Highway 345 district. Documentation shall be submitted that is signed and sealed from a North Carolina licensed engineer that the replacement tower meets the structural requirements of the North Carolina building code and a professional engineering certification which states that the structure's construction will cause the tower to crumble inward so that in the event of collapse, no damage to surrounding structures will result. Lighting of the tower shall be according to all Federal Communications Commission and Federal Aviation Association standards.

(17) Residential recovery and treatment center to include housing in multifamily structures and educational training. Center can be located in a single structure or multiple structures on one parcel of land. If more than one structure on parcel, it will be considered a group development subject to conditional use permit review according to Section 22-31 of the Dare County Zoning Ordinance.

(c) Conditional uses: Any use in existence on June 5, 2006 shall be allowed to continue in operation without seeking approval from Dare County, regardless if that use is listed as a permitted use or is listed as a conditional use in any of the Wanchese zoning districts. Additions or expansion of uses in existence on June 5, 2006 shall be subject to administrative review and approval by the Dare County Planning Department for compliance with the zoning regulations. Construction of additional principal use structures at existing business sites that would require a conditional use permit if not already established prior to June 5, 2006 shall trigger review and approval under the conditional use permit process.

The following conditional uses and no other conditional uses may be permitted, subject to the requirements of this district and the regulations and requirements imposed by the Board of Commissioners as provided by Article IX of this chapter. Any use not permitted herein shall be deemed prohibited.

(1) Boat building facilities.

(2) Churches, fire stations, cemeteries, and other public buildings.

(3) Telecommunication tower only associated with a principal use that is authorized as either a permitted use or conditional use in this district and subject to all standards established in Section 22-29.2 of the Zoning Ordinance.

(4) Home occupations as defined in Section 22-2.

(5) Elder in-home care, up to 4 non-related patients (private home nursing) provided the following minimum requirements are met:

**a.** Employee and visitor parking according to Section 22-56 in addition to 1 parking space for each non-resident employee.

b. Other reasonable conditions imposed by the Board of Commissioners.

(6) Fuel storage only associated with on-site business use.

(7) Group development housing projects according to Section 22-31 plus the following requirements:

**a.** Density shall not exceed 1 unit per 20,000 square feet of soils not classified as coastal wetlands; duplex home 25,000 square feet of soils not classified as coastal wetlands provided this area may be reduced to 20,000 square feet if duplex is served by central water supply.

**b.** Every dwelling unit shall be accessible to emergency service vehicles and Dare County Public Works vehicles.

c. Turning lane into project shall be provided with additional setback buffer along state-maintained rights-of-way into the residential neighborhoods.

d. Building height limit of 40 feet as defined in this section.

e. No mooring of permanent floating homes and other permanent floating structures as defined in 15A NCAC 7M00602 in the surrounding public trust waters of Dare County.

f. Accessory dwelling units are not allowed in sites developed as a group housing development.

g. A traditional village business use is not allowed in sites developed as a group housing development.

h. Other requirements that may be imposed by the Board of Commissioners.

(8) Commercial group development projects (more than one principal structure per parcel under single ownership) according to Section 22-31.

(9) Marinas, boat dockage, village marina store with fuel pumps, boat rentals for fishing excursions, and other non-motorized boat rentals provided the following minimum conditions are met:

**a.** Lot size shall be sufficient to meet requirements of the Dare County Health Department and to provide adequate siting for structures, parking, loading and maneuvering space as provided in Section 22-56.

**b.** Food and beverage service and/or a restaurant may be associated with a marina.

c. All boat rentals, except for fishing excursion rentals, shall be limited to non-motorized vessels and shall be limited to a total of 10 vessels offered for rent.

**d.** Fuel pumps shall not be located within 50 feet of a residential zoning district or residential use and that such fuel pumps shall be setback a minimum of 25 feet from all rights-of-way.

e. One 10' x 20' parking space shall be provided for each wet boat slip.

**f.** Outdoor lighting shall be complete cut-off design, low-profile, shielded and oriented in such a manner to minimize spill across property lines and prevent glare at any location on or off the property. A lighting plan shall be submitted as part of the site plan.

g. Subject to the other requirements of the Zoning Ordinance and other reasonable conditions as may be imposed by the Board of Commissioners.

(10) Public and private utilities (shall provide a planted vegetative buffer 10 feet in height).

(11) Private meeting and recreational facilities such as an event center for weddings and group parties, including private boat launching areas, tennis courts, picnic areas, private swimming pools and beaches, whereby catering is an integral part thereto. The following minimum requirements shall be met:

**a.** Parking for the event center and associated uses shall be based on the maximum occupancy of the proposed structure. Maximum occupancy shall be determined according to the North Carolina state building codes. One 10' x 20' space for every 4 persons or a minimum of 30 spaces whichever is greater.

(12) Pet grooming provided the following minimum requirements are met:

a. Shall be owner and/or family occupied residential premises.

**b.** Day care only for grooming – hours of operation limited to 7:00 a.m. to 6:00 p.m.

c. No outdoor run facilities and no overnight guests (not a kennel).

d. Other reasonable conditions imposed by the Board of Commissioners.

(13) Restaurants, food service, café provided the minimum following conditions are met:

a. Lot size shall be sufficient to meet requirements of the Dare County Health Department and to provide adequate siting for structures, parking, loading and maneuvering space as provided in Section 22-56. In addition, a fence or vegetative buffer shall be provided adjacent to residential use or residential zoning district.

**b.** The restaurant shall not feature drive-thru window service whereby patrons are served while seated in a motor vehicle or drive-up wait service whereby patrons are served while seated in a motor vehicle.

c. The restaurant shall include facilities for indoor and outdoor seating.

**d.** On-site parking shall be according to Section 22-56 – one 10' x 20' parking space for every 3 customer seats plus one 10' x 20' space for every 3 employees and loading space.

e. Outdoor lighting shall be complete cut-off design, low-profile, shielded and oriented in such a manner to minimize spill across property lines and prevent glare at any location on or off the property. A lighting plan shall be submitted as part of the site plan.

f. Other reasonable conditions as may be imposed by the Board of Commissioners.

(14) Retail garden shops and landscaping business may be permitted, subject to requirements of this chapter, provided the following minimum conditions are met:

**a.** Storage of mulch material may be allowed for retail sale only. Storage "stockpiles" shall not exceed 6 feet in height and no more than 3 stockpiles allowed for each site. Industrial production of mulch is not permitted.

**b.** One accessory greenhouse for storage and outdoor protection of plants is permitted. Greenhouse is not to be used for wholesale growing of plants.

c. Associated equipment used by the landscape business such as trailers, lawn mowers, single-axle trucks and tractors may be stored on the site. Storage area that is well buffered from general public may include draglines, bulldozers backhoes and other heavy equipment.

d. Storage areas of mulch and equipment shall be buffered with fencing.

e. Outdoor display and storage of plants, bags of soil, mulch, fertilizer, landscaping stone, landscape timbers, yard ornaments, and the like shall not restrict parking areas. Bags of mulch, soil, and the like shall be stacked in an orderly manner.

f. Bulk irrigation piping shall be stored indoors.

g. Other conditions imposed by the Board of Commissioners.

(15) Storage/warehousing and warehouse storage centers, including boat trailers and long-term storage containers and mobile storage, provided the following minimum conditions are met:

**a.** Site shall be buffered with wooden opaque fencing not to exceed 10 feet in height and also provide sound and site screening as visual and sound buffer to residential homes in and around area of warehouse storage site.

**b.** Outdoor lighting plan shall be submitted with a site plan.

c. Hours of operation shall be included as part of CUP review.

d. Other reasonable conditions as may be imposed by the Board of Commissioners.

(16) Village center project: a mixed use development situated on single parcel of land under single ownership whereby an existing commercial building, or new structure, may be developed and limited to

retail sales units on the lower level of the structure with residential units on upper level. Additional residential units may be situated on the site. The following minimum requirements shall be met:

a. Village center complex site must contain a minimum of 3 acres.

**b.** Approval of all supplementary local, state and federal permits. Site must be adequate for siting commercial structure, parking, loading and maneuvering space as required by Article VII. Two 10'x 20' parking spaces per residential use shall be provided. Overflow parking, if applicable, shall be directed to off peak use of commercial spaces.

c. Site screening - a vegetative or fence buffer not to exceed 10 feet in height. A 10-foot wide setback shall be required where the site abuts a residential use or zone (not subject to 20-foot dimensional requirements in D.1 - D immensional requirements).

**d.** Food service shall be limited to packaged items, such as snacks, drinks and ice cream. Food service may be located outside the building on site as a refreshment pavilion to serve patrons in the village complex. Food service shall be exempt from parking as required for restaurants.

(17) Village general store with fuel pumps provided that no principal or accessory building shall be located within 50 feet of a residential use, accessory dwelling unit, or residential district and that such fuel pumps shall be set back at least 25 feet from all rights-of-way. The following minimum requirements shall be met for open canopy lighting to preserve the night time environment :

**a.** The area directly below the canopy may be illuminated with a minimum foot candle of 4 but not to exceed a foot-candle rating of 10.

**b.** Parking spaces provided under a canopy shall be 10' x 20' in area.

(18) Spoil sites for maintenance dredging.

(19) Wind energy research facilities according to the standards of Section 22-29.3. (Adopted 4-18-11)

(20) Temporary, portable concrete plant including silos, aggregate bins, dust collector, hoppers, conveyors, batch mix, office and other accessory equipment necessary to the operation of the portable concrete plant including storage of aggregate and other materials necessary for the making of concrete.

**a.** The lot or parcel upon which the portable concrete plant is located shall contain at least four (4) acres of contiguous non-wetland area.

**b.** The plant and all accessory equipment shall be mobile and may be not permanently attached to the property. The equipment may be temporarily secured to the property for safety reason but must be removed upon the expiration of the conditional use permit.

c. Notwithstanding any other provision of the Zoning Ordinance, the portable concrete plant when erected shall not exceed 60 feet in height.

**d.** The concrete plant and storage of aggregate and other materials shall be at least twenty-five (25) feet from any property line and there shall be wooden opaque fence no less than ten (10) feet high between the plant and any residence or residential zone.

e. The concrete plant shall include a dust collection system which collects dust at the load out point and the particulate that is collected is recycled into the system.

f. All aggregate stored on the site shall be kept moist at all times to prevent dust.

**g.** All outdoor lighting shall be low profile, shielded with glare directed on-site and away from any adjoining properties and streets.

**h.** No more than eight (8) trucks used for the transport of concrete may be parked overnight on the property.

i. There shall be no concrete transport trucks that enter or exit the site between the hours of 7:00 a.m. to 8:30 a.m. and 2:00 p.m. to 3:30 p.m. on any day public schools in Dare County are in session.

**j.** The concrete plant shall be operated in accordance with all requirements of the North Carolina Department of Transportation and any other regulatory body.

**k.** This conditional use permit shall remain in effect for a period of 39 months. This 39-month period shall commence on the date identified by NC Department of Transportation in the notice to proceed issued by NCDOT to the bridge contractor. Upon the showing of good cause, the Dare County Board of Commissioners may extend the permit for up to 180 additional days. Good cause shall mean unavoidable conditions or events necessitating the continued operation of the plant for the purpose for which it was originally installed.

**1.** Upon expiration of the conditional use permit, operation of the concrete plant shall cease and the concrete plant and all accessory equipment and materials shall be removed from the site and the site returned to its original condition within thirty (30) days.

m. A performance bond, satisfactory to Dare County, to be used for removal and reclamation activities shall be established by the permittee at the time a site specific development plan and conditional use permit for a temporary portable concrete plant is authorized by Dare County. The bond shall be in the amount of \$20,000 shall be issued to Dare County to be used in the event the permittee does not remove all equipment from the site and restore the site to its original condition as provided above. If this amount is insufficient to cover the cost of reclamation of the site, then the property owner shall be held accountable for the additional amount and a lien shall be placed on the site for any amount over the \$20,000 bond amount that is incurred by Dare County in the reclamation of the site. The bond shall remain in place until released by Dare County upon certification by Dare County of compliance with the conditions of this permit. Dare County shall be authorized to use the bond to cover all costs and expenses of removal, including but not limited to all legal fees or other costs or expenses associated with enforcement of the provisions of the conditional use permit. This bond shall be forfeited if the concrete plant, all equipment, components and accessories of the concrete plant have not been removed from the site and the site restored to its pre-plant conditions within the time required by this conditional use permit. In lieu of a bond, permittee may post a cash bond with Dare County to be held for the purposes set forth above. (Adopted 11-19-2012)

#### (d) Dimensional requirements for residential uses:

(1) Minimum lot size:

**a.** Single-family lots with accessory dwelling units and accessory commercial structures used in association with a single-family use shall be of sufficient size to meet the requirements of the Dare County Environmental Health Department and to provide adequate setbacks for the single-family structure, accessory dwelling unit and all other accessory use structures.

Existing lots – All lots that were subdivide and recorded before June 5, 2006 shall meet the approval of the Dare County Environmental Health Department for well and on-site wastewater systems. The setbacks and lot coverage standards of Section 22-27.18 shall apply to lots recorded June 5, 2006.

**b.** Newly platted lots -- For those lots subdivided and recorded after June 5, 2006:

Single family lots:

15,000 square feet of soils not classified as coastal wetlands for lots connected to a central water supply.

20,000 square feet of soils not classified as coastal wetlands for lots connected to a private well.

Duplex lots: 25,000 square feet of soils not classified as coastal wetlands.

(2) Minimum lot width: 75 feet at building setback line.

(3) Minimum front yard: 25 feet.

(4) Minimum side yard: 10 feet; an additional 5-foot side setback for corner lots adjacent to a street. Lots less than 75 feet in width shall have an 8-foot setback and an additional 5-foot setback for corner lots adjacent to a street.

(5) Minimum rear yard: 20 feet maximum, or 20% of lot depth. Zero line setback for waterfront lots.

(6) Lot coverage: 30% as defined in Section 22-2. Lot coverage of 50% may be authorized for those sites with an accessory dwelling unit and/or a traditional village business.

(7) Building height: 40 feet to the highest elevation of any feature of the structure or portion of the roof measured from the base flood elevation, from natural ground elevation if natural ground elevation exceeds the base flood elevation, or from an unnatural ground elevation created by placement of fill material on a site on or before June 5, 2006. Chimneys, lightning rods, weather vanes, wind gauges, and other similar roof appurtenances shall not be considered the highest portion of the roof. The pitch of the principal roof shall be no less than 4/12. Principal roof is defined as the largest section of roof on the structure.

# (e) Dimensional requirements for individual commercial use on separate lot or parcel that is not in conjunction with principal residential use:

(1) Minimum lot size: Commercial lots need to be of sufficient size to meet the requirements of the Dare County Environmental Health Department and to provide adequate siting for structures, parking, loading and maneuvering space according to Section 22-56. Also, a visual buffer of vegetation of fencing and a 20-foot wide setback is required when an individual commercial use abuts a residential use or residential zone. All outdoor lighting shall be low profile, shielded with glare directed on site and away from all adjoining properties and streets.

(2) Minimum front yard: 15 feet.

(3) Minimum side yard: 10 feet; an additional 5-foot side setback for corner lots adjacent to a street. Lots less than 75 feet in width shall have an 8-foot setback and an additional 5-foot setback for corner lots adjacent to a street.

(4) Minimum rear yard: 20 feet maximum, or 20% of lot depth for interior lots. Zero line setback for waterfront lots.

(5) Lot coverage: 60% as defined in Section 22-2.

(6) Building height: 40 feet to the highest elevation of any feature of the structure or portion of the roof measured from the base flood elevation, from natural ground elevation if natural ground elevation exceeds the base flood elevation, or from an unnatural ground elevation created by placement of fill material on a site on or before June 5, 2006. Chimneys, lightning rods, weather vanes, wind gauges, and other similar roof appurtenances shall not be considered the highest portion of the roof. The pitch of the principal roof shall be no less than 4/12. Principal roof is defined as the largest section of the roof on the structure.

(7) Maximum commercial building size: 10,000 square feet of heated space excluding decks, porches, and other non-heated space. Non-heated space shall not exceed 20,000 square feet of area. The total building size shall not exceed 30,000 square feet based on these heated/non-heated square footage limitations. Hotels, motels, churches, fire stations, schools and other public buildings are excluded from this building size limitation.

(8) Density limitations for motels, hotels, and similar seasonal lodging structures:

**a.** Structures on a lot or tract that has no soils classified as wetlands, coastal marsh or section 404 jurisdictional soils: 10 rental rooms per acre.

**b.** Structures on a lot or tract that has between .01% and 19.9% of its soils classified as wetlands, coastal marsh, or section 404 jurisdictional soils: 8 rental rooms per acre.

**c.** Structures on a lot or tract that has more than 20% of its soils classified as wetlands, coastal marsh or section 404 jurisdictional soils: 6 rental rooms per acre.

(f) Non-conforming uses and non-conforming structures: The standards of Section 22-27.19 shall apply to this district.

(g) Performance standards and other information: The standards of Section 22-27.20 shall apply to this district.

(h) The sections contained in Articles I, Article III, Article VII, Article VIII, and Article IX of the Dare County Zoning Ordinance shall apply to this district.

(Adopted by the DCBC on June 5, 2006; amended 2-20-2017; amended 11-20-2017)



System Development Fee Calculation Required by NCGS 162A Article 8

## Description

Please the attached Item Summary.

Attachments: Item Summary System Development Fee Report

## **Board Action Requested**

The Board is requested to schedule a public hearing as required by HB 436.

### **Item Presenter**

David Clawson, Finance Director

#### Item Summary: System Development Fee Calculation Required by NCGS 162A Article 8

House Bill 436 (Session Law 2017-138 - the Public Water and Sewer System Development Fee Act) states that a unit of local government may only impose a System Development Fee (formerly known as impact fee) if it has complied with HB 436. HB 436 requires a calculation of the fee and provides what professionals may perform the calculation, all of the calculation methods that may be used, and certain calculation requirements. The calculation must be repeated at least once every five years.

The County contracted Raftelis Financial Consulting to perform the calculation. The County contracts Raftelis to perform the annual rate model update, all revenue bond feasibility studies, and the 2016 Rate Structure Study.

Raftelis delivered the final report on 3/7. As required by HB 436 the report was posted to the County website on 3/9 for a 45 public comment period. No comments were received.

#### Effects

The first effect of the study is that the County may not charge its Expanding Area Policy Fee after 6/30/2018. Total revenue from that fee over the last five years was \$6,000.

The second effect is the calculated allowed charges for System Development Fees per the below.

Meter Size	Current # of Active Meters	Existing Fee	7/1/2018 Maximum Allowed Fee		
<sup>3</sup> / <sub>4</sub> inch	15,576	\$2,500	\$2,405		
1 inch	1,262	\$3,000	\$4,008		
1 ½ inch	162	\$3,500	\$8,017		
2 inch	81	\$4,000	\$12,827		
3 inch	11	\$5,000	\$24,050		
4 inch	8	\$6,000	\$40,083		
6 inch	5	\$8,000	\$80,166		

The change in the fees for larger meters is due to NCGS 162A-205(6) that requires the use of an equivalency or conversion table, the standard for which is per the AWWA M-1 Manual, which was used by Raftelis. This ensures that each meter size is charged equally for its relative demand upon the system.

The fees listed are the maximum allowed by HB 436. The Board may adopt lower fees but each calculated fee must be adjusted equally. For example, if the 6 inch meter fee was lowered to 25% of the maximum allowed, then every fee would have to be lowered to the same 25% of the maximum allowed.

The Maximum Allowed Fee for each meter size is expected to be revenue neutral to the Water System. Past Impact Fee revenues have been \$387,377 for 2017, \$459,837 for 2016, and \$398,385 for 2015.

#### Public Hearing and Adoption

The Board is required by HB 436 to hold a public hearing "to consider adoption of the analysis with any modifications or revisions". After the Public Hearing, the fee structure may be adopted as of 7/1/2018 as a part of the annual budget ordinance.

The Board is requested to schedule the public hearing.



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February 26, 2018

Mr. David Clawson Deputy County Manager/Finance Director Dare County Finance 954 Marshall C. Collins Drive Manteo, North Carolina 27954

Dear Mr. Clawson:

Raftelis Financial Consultants, Inc. (Raftelis) has completed its assignment to develop costjustified water system development fees for consideration by the County of Dare (the County). This letter documents the results of the analysis which is based on a cost justified approach for establishing system development fees (impact fees) as set forth in North Carolina general statute 162A Article 8 "System Development Fees".

Raftelis is a financial consulting firm that has provided rate and financial consulting to public water and wastewater utilities since 1993, has edited or contributed content for the Seventh Edition of the American Water Works Association "Principles of Water Rates, Fees and Charges M-1 Manual" (AWWA M-1 Manual), and has calculated impact fees for utilities in North Carolina and across the country since 1993 using generally accepted methodologies as provided in the AWWA M-1 Manual and other water/sewer industry publications. Raftelis is qualified to perform system development fee calculations for water and wastewater utilities in North Carolina.

#### Background

System development fees are defined as one-time charges assessed to new water customers, or developers and builders, to recover a proportional share of capital costs incurred to provide service availability and capacity for new utility customers. Typically, the cost basis for setting system development fees is based on the major system components, or core system assets, that are necessary to serve, and that provide benefit to, all customers. These components typically include reservoirs, water treatment plants, storage tanks, major water transmission lines, and pumping stations.

Raftelis recommends that system development fee calculations be consistent with the common legal standard in setting system development fees in the water industry – the Rational Nexus Test. The Rational Nexus test requires that: 1) the need for capacity is a result of new development; 2) the costs are identified to accommodate new development; and 3) the appropriate apportionment

of that cost to new development is in relation to the benefit the new development reasonably receives<sup>1</sup>.

There are three approaches, as described below, for calculating water system development fees that are recognized in the industry as cost-justified<sup>2</sup> (that meet the requirement of the Rational Nexus standard), and as set forth in North Carolina general statute 162A Article 8 "System Development Fees".

## Buy-In Approach

The Capacity Buy-In Approach calculates a system development fee based upon the proportional cost of each user's share of existing system capacity, and is most appropriate in cases where the existing system assets provide adequate capacity to provide service to new customers. The cost of the facilities is based on fixed asset records and can include escalation of the depreciated value of those assets to current dollars, or "replacement costs" as identified in the general statute. The general statute also identifies adjustments to be made to the replacement cost such as "debt credits, grants, and other generally accepted valuation adjustments."

### Incremental Cost Approach

The Incremental Cost (or Marginal Cost) Approach calculates a system development fee based upon a new customer's proportional share of the incremental future cost of system capacity. This approach focuses on the cost of adding additional facilities to serve new customers. It is most appropriate when existing facilities do not have adequate capacity to provide service to new customers, and the cost for new capacity can be tied to an approved capital improvement plan (CIP) that covers at least a 10-year planning period. Per the general statute, a revenue credit must be applied "against the projected aggregate cost of water or sewer capital improvements".

#### Combined Approach

The Combined Approach is a combination of the Buy-In and Incremental Cost approaches, and is appropriate to be used when the existing assets provide some capacity to accommodate new customers, but where the capital improvement plan also identifies significant capital investment to add additional infrastructure to address future growth and capacity needs.

## Calculation of System Development Fees

Raftelis requested and was provided with the following data from County staff to complete the impact fee calculation:

- Water system fixed asset data;
- Outstanding utility debt and associated debt service;
- Construction work in progress ("CWIP");
- Contributed capital;
- Capacity of the water system;

<sup>&</sup>lt;sup>1</sup> See the AWWA M-1 7<sup>th</sup> Edition Manual –System Development Charges, Chapter VII2; pp.324.

<sup>&</sup>lt;sup>2</sup> See the AWWA M-1 Manual –System Development Charges, Chapter VII.2; pp.329-330.

- Daily water production data; and
- History of system development fees collected.

The Capacity Buy-In Approach was chosen as the method to calculate the system development fees. While the County has identified future water projects in its capital improvement plan, these projects are repair and replacement projects that will not expand capacity. Additionally, through discussions with County staff, Raftelis understands that the utility has enough current capacity to appropriately serve its current and planned customers.

Using the Capacity Buy-In approach, Raftelis calculated the estimated cost, or investment in, the current capacity available to provide utility services to existing and new customers. This analysis was based on a review of fixed asset records and other information as of June 30, 2017. The depreciated value of the assets was first adjusted to reflect an estimated replacement cost to determine the "replacement cost new less depreciation" (RCNLD) value for the assets. The asset values were escalated using the Handy Whitman Index of Public Utility Construction Costs (for the South Atlantic Region). The RCNLD value of the water assets includes water supply, treatment, storage, distribution facilities, and construction work in progress (CWIP) for FY2018, but excludes small equipment, meters, vehicles and other rolling stock.

Several larger adjustments were then made to the RCNLD value, to calculate a net value of the system, which were as follows:

- Subtraction of contributed capital and grant funded assets two types of capital were excluded from the total value of the system used for fee calculation: grant funded assets and capital contributed to the system by developers. The rationale for excluding the value of this capital is that the water utility, and thus the existing customers of the system, did not pay for these assets. For contributed assets, Raftelis cross referenced the fixed asset records with a list of donated assets, provided by the County, and excluded any donated assets that were also listed in the fixed asset ledger. For grant funded assets, provided by the County, and removed any donated assets that were listed on both schedules.
- *Debt credit* Utilities often borrow funds to construct assets, and revenues from fees and retail rates and charges can be used to make payments on these borrowed funds. To ensure that new customers are not double charged for these assets, once through impact fees and twice through retail rates and charges, a proportion of the outstanding principal debt is credited towards the net value of the system. This proportional amount was estimated by comparing the historical annual amount of revenues collected from system development fees with the respective, historical annual amount of principal payments. Since the County applies revenues from system development fees to offset outstanding debt service, and since the County's bond ordinance allows the inclusion of system development fees

to be used in meeting debt service coverage requirements, the amount of the debt credit was calculated as the principal amount of outstanding debt less the proportion of the principal amount estimated to be paid for with system development fee revenues.

The net system value: total RCNLD, minus contributed assets, grant funded assets, and the debt credit, was then converted to a unit cost of capacity by dividing the adjusted RCNLD value by a basic unit measure of cost per gallon per day (GPD) for water capacity, as shown in Exhibit 1.

## Exhibit 1 – Cost per GPD of Core Utility Assets

	Water
Net System Value	\$65,262,824
Total Capacity (gallons per day)	13,316,000
Cost Per Gallon per Day	\$4.90

System cost per gallon per day becomes the basic building block, or starting point, for determining the *maximum cost-justified level* of the water system development fees.

The next step is to define the level of demand associated with a typical, or average, residential customer, often referred to as an Equivalent Residential Unit, or ERU. The level of demand associated with a typical residential customer is often estimated using wastewater design flow rates as specified by the North Carolina Administrative Code Title 15A (Department of Environment and Natural Resources) Subchapter 2T, which states that the sewage from dwelling units is 120 gallons per day per bedroom. Based on input from County staff regarding residential homes, number of bedrooms, and rental properties the average gallons per day used was the average of the 2 and 3-bedroom home (which is 300 gallons per day per ERU). Since the ERU of 300 gallons per day represents average use, to estimate the peak day water use for the County's customers, a peaking factor (based on daily water production records for FY2015 through FY2017) was applied to derive an adjusted ERU of 491 gallons per day, as shown in Exhibit 2. Because Dare County's water system faces wide variation in demand based on season, application of a peaking factor appropriately represents the actual demand placed by a residential unit on the system.

## **Exhibit 2: Water Demand per Residential ERU**

	Water – gallons
	per day per ERU
ERU Per State Guidelines	300
Peaking Factor	1.64
Adjusted ERU	491

## **Assessment Methodology**

This analysis provides a maximum cost-justified level of system development fees that can be assessed by the County. The calculation of the system development fee for a <sup>3</sup>/<sub>4</sub> inch meter is based on the cost per gallon per day multiplied times the number of gallons per day required to serve each ERU, as shown below in Exhibit 3.

## Exhibit 3 – Calculated Maximum Residential Capacity Fee

Residential	Water
Cost per GPD	\$4.90
GPD per ERU	491
Total Calculated Capacity Fee per ERU	\$2,405
Existing Capacity Fee per ERU	\$2,500

For customers with larger meter sizes, the fees for the smallest residential meter can be scaled up by the flow ratios for each meter size, as specified in the AWWA M-1 Manual<sup>3</sup>, the results of with are shown in Exhibit 4. This method provides a straightforward approach that is simple to administer and reasonably equitable for most new customers.

Exhibit 4 shows the resulting maximum cost-justified system development fees by meter size for meters ranging from 3/4 inches to 6 inches. For these calculations, the system development fees have been rounded to the nearest dollar.

<sup>&</sup>lt;sup>3</sup> See the AWWA M-1 Manual – Appendix B- Equivalent Meter Ratios; pp.386

Meter Size	Existing Fees	Maximum Cost Justified Fees
3/4"	\$2,500	\$2,405
1"	\$3,000	\$4,008
1.5"	\$3,500	\$8,017
2"	\$4,000	\$12,827
3"	\$5,000	\$24,050
4"	\$6,000	\$40,083
6"	\$8,000	\$80,166

## Exhibit 4– Calculated Maximum System Development Fees for Non-Residential Customers

The County may elect to charge a cost per gallon that is less than the maximum cost justified amount documented in this report. If the County elects to charge a fee that is less, all customers must be treated equally, meaning the same reduced cost per gallon per day must be used for all customers.

We appreciate the opportunity to serve the County of Dare with this important engagement. Should you have any questions, please do not hesitate to contact me at (704) 936-4436.

Very truly yours, RAFTELIS FINANCIAL CONSULTANTS, INC.

Caine Contr

Elaine Conti, Senior Manager

## Appendix

## Supporting Schedules From the System Development Fee Model

## County of Dare, NC Supporting Schedule 1 – Fee Calculation

Water System RCNLD - Unadjusted		
Cape Hatteras Water Plant	\$	23,249,595
North Reverse Osmosis Plant		24,963,492
RWS Reverse Osmosis Plant		6,595,392
Skyco Water Plant		13,190,569
Stumpy Point Water		9,723,748
Surplus		4,299
Water Administration		2,114
Water Distribution		14,751,210
Total System Cost	\$	92,480,421
Ineligible Assets - Adjustments		
Cape Hatteras Water Plant	\$	(77,742)
North Reverse Osmosis Plant		(24,746)
RWS Reverse Osmosis Plant		(3,906)
Skyco Water Plant		(15,765)
Stumpy Point Water		(9,723,748)
Water Distribution		(414,949)
Total Deductions	\$	(10,260,856)
N) Net Water System RCNLD - Adjusted		
Total Adjusted System Cost	\$	82,219,565
3) <u>Additions</u>		
Construction Work in Progress		
Water CP - Skyco	\$	22,353
Skyco Nanofiltration		7,404
Skyco Media (FY15 E&R)		7,309
Skyco WTP Phase I & II		14,950
Skyco WTP Phase I & II (FY15 E&R)		6,697
Skyco WTP Nanofiltration Phase III	_	2,123
Total CWIP	\$	60,837
Adjusted System Cost (A + B)	\$	82,280,402
Outstanding Principal	\$	29,070,000
Percent of Credit Included		58.5%
0) Net Debt Service Credit	\$	17,017,578
) Net Value (C - D)	\$	65,262,824
) Existing System Capacity (in GPD)		13,316,000
6) Cost per GPD (system) (E / F)	\$	4.90
Calculation of ERU I) Daily ERU (in GPD)		300
) Peaking Factor		1.64
) Adjusted ERU (H * I)		491
() Highest Cost Justified Impact Fee	\$	2,405

# Supporting Schedule 2 – Removal of Contributed Capital & Non-Eligible Assets by Asset Class

Adjustments By Asset Class	
Rolling Stock	\$ 310,861
Meter related	6,728
Small equipment	281
Donated	219,238
Grant-Funded	9,723,748
Total Deductions	\$ 10,260,856

## Supporting Schedule 3 – Debt Credit Adjustment Calculation

2015 - 2016 Average Impact Fee Revenue	
Initial impact fee	\$ 337,813
Initial impact fee - RWS	21,300
Initial impact fee - CH	69,999
(A) Average Total Impact Fee Revenue	\$ 429,111
(B) 2015 - 2016 Total Average Annual Principal Payment	\$ 1,035,000
(C) Percent of Impact Fee Revenue Applied to Principal Annually (A / B)	41.5%
(D) Percent of Principal To Credit (1 - D)	58.5%
(E) Total Outstanding Principal	29,070,000
Amount of Principal to Credit (D * E)	17,017,578

## **Supporting Schedule 4 – Peaking Factor Data**

## **Peaking Factors**

	FY15	FY16	FY17	
Hatteras	1.61	1.91	1.61	
NRO	1.41	1.53	1.58	
R.I Excl. Manteo-Dare Co.	1.33	1.18	1.13	
Roanoke Island	1.37	1.26	1.33	
RWS	2.18	2.16	2.11	
Skyco (trans.)	1.97	1.92	1.84	
Stumpty Point	1.85	1.67	2.01	
Average Peaking Factors	1.60	1.67	1.64	
			3-yr A	verage:
				4 6 4

1.64



Series 2018 Limited Obligation Bonds – Decision on Issuance Type, Structure, and Financing Award

## Description

Please see the attached Item Summary.

Attachments are: 1) Item Summary; 2) Options Analysis; 3) Financing Proposal Results; and 4) Term Sheet for Proposals.

#### **Board Action Requested**

The Board is requested to award the Series 2018 LOBs as a private placement with a current settlement on ~July 19, 2018 to Regions Bank at a rate not to exceed 2.72%.

#### **Item Presenter**

David Clawson, Finance Director

### <u>Item Summary:</u> Series 2018 Limited Obligation Bonds – Decision on Issuance Type, Structure, and Financing Award

#### Background & Timing

The Series 2018 Limited Obligation Bonds (LOBs) will be issued for part of the County's contribution to the Nags Head beach nourishment maintenance project (\$9,573,356) and for improvements to Manteo High School per the approved CIP (\$590,000).

Since the beach nourishment bids resulted in a 2019 project, and to allow time for the FEMA funding approval for the bid alternate project, Nags Head has pushed Local Government Commission (LGC) approval to July 10.

Based on the original LGC approval date of June 5, the County's underwriter/placement agent, Piper Jaffray, issued a Term Sheet (4<sup>th</sup> attachment) on March 22 requesting private placement financing proposals, which were due April 13. Proposal results are the 3<sup>rd</sup> attachment.

The Board normally awards the financing award in the initial bond resolution, but since the LGC approval has been pushed to July, the initial resolution will not be to the Board until June. Therefore the Board is being asked to make a financing award now.

#### **Debt Structure Options**

Both a public bond offering and a private bank placement were evaluated on a current basis and on a forward basis. A current would close in July. A forward would close in January, saving six months of interest but at a higher interest rate and with certain rate reset and withdrawal risks.

#### Public Sale versus Private Sale

With the private placement proposals, the costs of a public bond sale were also analyzed (2<sup>nd</sup> attachment). Based on estimates as of 4/24, a current public sale would be slightly less expensive than the private placement at a True Interest Cost (TIC) of 3.157% versus 3.167%. The forward public sale is estimated at approximately equal to a private placement at TICs of 3.834% versus 3.833%.

However, the analysis uses an estimate of what market rates would be in July on the sale date for a public offering. Given the rising interest rate environment, staff, DEC & Associates (financial advisor), and Piper Jaffray (underwriter/placement agent), all recommend that the County eliminate that interest rate risk and lock in an interest rate by using a private placement.

#### Current versus Forward

The two low proposals for a private placement were Regions Bank at 2.72% for a current and Capital One Public Funding at 3.25% for a forward. Without six months of interest costs, the forward, at a TIC of 3.833% has a lower interest cost of approximately \$15,000 than the current at a TIC of 3.167%.

However, a forward settlement will contain certain conditions relating to natural disasters, lawsuits, and changes in County representations, which would allow the provider to reset the interest rate or withdraw the financing commitment. Given those risks and the low cost of eliminating those risks, staff, DEC & Associates, and Piper Jaffray, all recommend that the County utilize the current settlement option.

#### Financing Award

The Board is requested to award the Series 2018 LOBs as a private placement with a current settlement on ~July 19, 2018 to Regions Bank at a rate not to exceed 2.72%.

	General M	<u>larket</u>	Private Placement
Scenario	Current	Forward	Current Forward Regions Capital One
Dated/Deliver	7/26/2018	1/19/2019	7/12/2018 1/19/2019
Total Par	9,960,000	10,140,000	10,295,000 10,300,000
Premium	483,550	306,495	
Total Proceeds	10,443,550	10,446,495	10,295,000 10,300,000
COI U/W Discount	212,500	212,500	93,750 101,250
/Placement Agent	62,748	63,882	30,885 30,900
Total COI	275,248	276,382	124,635 132,150
Total DS	11,077,274	11,092,495	11,102,908 11,092,242
Total Interest	1,117,274	952,495	807,908 792,242
Net Interest	696,471	709,882	807,908 792,242
All-in TIC	3.157%	3.834%	3.167% 3.833%
Arb. Yield	2.159%	2.629%	2.720% 3.250%

Dare S2018 LOBs

	Southern							
Proposer	Bank	KGF	First Bank	CapOne	PNC	Regions	Pinnacle	Sterling
Current	3.40%	3.04%	3.35%	3.08%	3.06%	2.72%	3.35%	2.91%
Forward	3.40%		3.55%	3.25%	3.28%			
Origination	5,000	-	5,000					
		Mth 1-36 @ 0.75%, par				5% for 1st year; 4% 2nd; 3% 3rd; 2% 4th;		Non-call Year 1-2, 101% in year 3,
Prepayment		therafter	Anytime	??	Make-whole	and 1% in 5th		par thereafter
Fees	Bank Counsel	Bank Counsel NTE \$20,000	Bank Counsel NTE \$5,000		Bank Counsel NTE \$10,000	Bank Counsel NTE \$7,500		None
Event of Taxability/Gross up		Usual/customary		??	Yes	Yes		
Margin Rate				??	yes			
Appx. All-in TIC (excluding								
Bank Counsel)	3.86%	3.500%	3.810%	3.540%	3.520%	3.167%	3.810%	3.374%

### TERM SHEET

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"Institutional Accredited Investors" with person has been authorized by the Issuer any representations other than those com relied upon as having been authorized b purchase and acceptance of a Bond, an concerning the Issuer and the Bonds as s	red solely pursuant to this Term Sheet to a limited number of "Qualified Institutional Buyers" or hin the meaning of the Securities Act of 1933, as amended. No dealer, broker, salesp erson or other (as defined herein) or Piper Jaffray & Co., as Placement Agent, to give any information or to make tained in the Term Sheet, and if given or made, such other information or representations must not be y any of the foregoing. By execution and delivery of an Investment Letter (as defined herein) and the y such purchaser thereof shall be deemed to have had access to such financial and other information when purchaser deemed necessary to make an independent investment decision to purchase the Bonds, letime prior to such purchase, to ask questions of and receive answers concerning the Issuer and the e Bonds and the security therefore.
Issuer:	Dare County, North Carolina through its Dare County Public Facilities Corporation (the "County").
Issue:	Dare County NC, Limited Obligation Bonds, Series 2018 (the "Bonds")
Purpose:	Proceeds of the Bonds will be used for \$590,000 in improvements to Manteo High School and a \$9,573,356 beach nourishment project at Nags Head, and issuance costs for the Bonds. The total cost of the Nags Head project is \$41,546,711 and the County has agreed to pay for \$12,573,356 of this amount. Of this amount, the County will pay \$3,000,000 in cash and issue \$9,573,256 of LOBs. The \$3,000,000 cash portion will be paid to the Town of Nags Head in 5 annual payments of \$600,000. The Town of Nags Head will issue Special Obligation Bonds to pay their \$12,973,356 share of the project. FEMA will pay the remaining \$16,000,000 balance for the project.
Par Amount*:	Approximately \$10,295,000
Dated/Closing Date*:	Either: 1) June 14, 2018, or 2) January 17, 2019 if a forward delivery. See "Bidder Rate Quotes" section below.
Bids Due to Piper:	Friday, April 13, 2018
Principal Payment Dates:	June 1st, beginning $6/1/19$ with a final maturity of $6/1/23$ .
Interest Payment Dates:	December 1 <sup>st</sup> and June 1 <sup>st</sup> , beginning either 1) December 1, 2018 for a June 2018 current interest closing, and 2) June 1, 2019 for the

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\*Preliminary, subject to change.

#### **TERM SHEET**

	forward delivery option. Both options outlined below in "Bidder Rate Quote".
Rating:	The Issuer will not seek a rating on the Bonds. The County's current LOBs bond ratings are: Aa3/AA//AA-
Tax Status:	Interest on the bonds will be tax exempt.

Current Amortization: \*

	Series 2018
6/1/2019	\$2,060,000
6/1/2020	2,060,000
6/1/2021	2,060,000
6/1/2022	2,060,000
6/1/2023	2,055,000
Total	\$10,295,000

Bidder Rate Quote:

Bidders are requested to provide *fixed interest rate* for either or both of the following:

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- 1) *Current Interest Rate:* a single interest rate or an interest rate scale by maturity for the Bonds assuming a closing on June 14, 2018, or
- 2) *Forward Interest Rate:* a single interest rate or an interest rate scale by maturity for the Bonds assuming a forward drawing/closing on January 17, 2019

Average Life (from closing)*:	2018 Closing	2019 Closing
	2.96 Years	2.37 Years

Prepayment Provision:

Piper Jaffray will entertain any prepayment provisions.

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## TERM SHEET

Security for the Bonds:	The County has previously entered into an Installment Purchase Contract dated as of December 1, 2005 (the "2005 Contract") with the Corporation in order to finance acquiring, constructing, renovating, improving, equipping and furnishing certain school facilities including Manteo Elementary School, Kitty Hawk Elementary School, Hatteras Secondary School and Manteo High School, and has previously entered into Amendment Number One to the Installment Purchase Contract dated as of February 1, 2013 (the "First Contract Amendment") with the Corporation to refinance various County projects.
	In June 2016, the County entered into another amendment to the 2005 Contract (the "Second Contract Amendment") with the Corporation, in order to finance the costs of an HVAC Chiller repair to Hatteras Secondary School and to complete a beach nourishment project at Buxton.
	For the Series 2018 financing, the County will enter into another amendment to the 2005 Contract (the " <i>Third Contract Amendment</i> " and together with the 2005 Contract, the First Contract Amendment and the Second Contract Amendment, the " <i>Contract</i> ") with the Corporation, in order to finance the costs of improvements to Manteo High School and a portion of the cost of a beach nourishment project at Nags Head as discussed in the "Purpose" section above.
	In order to secure its obligations under the Contract, the County granted a Deed of Trust and Security Agreement dated as of December 1, 2005 (the "Deed of Trust") on the real property on which Kitty Hawk Elementary School, Hatteras Secondary School and Manteo High School are located (the "Mortgaged Property"). The County will not add any additional property to the lien granted under the Deed of Trust in connection with the execution and delivery of the Bonds.
	The Bonds will be executed and delivered under an Indenture of Trust dated as of December 1, 2005, between The Bank of New York Mellon Trust Company, N.A., as trustee, and the Corporation, as amended and supplemented by Supplemental Indenture, Number 1 dated as of February 1, 2013 between the Trustee and the Corporation (collectively, the "2005 Indenture"), Supplemental Indenture, Number 2 dated as of May 1, 2016, and Supplemental Indenture, Number 3 dated as of June 1, 2018, between the Trustee

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\*Preliminary, subject to change.

and the Corporation.

#### TERM SHEET

The Bonds will be on parity with Refunding Limited Obligation Bonds, Series 2013 and the Series 2016B executed and delivered under the 2005 Indenture, and, as of June 14, 2018, will be outstanding in the aggregate principal amount of \$44,295,000, and \$37,785,000 after the June 1, 2018 principal payment.

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The \$72,464,500 combined value of the Mortgaged Property is in excess of the \$54,590,000 projected to be outstanding (after May 10, 2018) under the Contract. See below chart for detail.

County of Dare, North Carolina				
Collateral: Series 2005 COPs (no longer outstanding),	Series 2013A Refunding	LOBs, Series 2016	B LOBs and Series 2018 LOBs	
			Par Outstanding	Par Outstanding
	2005 Indenture		Series 2013, 2016B and 2018	Series 2013, 2016B and 2018
Collateral	Collateral Value		As of Closing 6/14/18	As of 1/17/2019
Hatteras Secondary School	26,648,200	Series 2013	19,890,000	19,890,000
		Series 2016B	17,895,000	17,895,000
Kitty Hawk Elementary School	15,511,900	Series 2018	10,295,000	10,295,000
Manteo High School	30,165,200			
Total	72,325,300		48,080,000	48,080,000

Additional Bonds: The County reserves the right to authorize and to issue additional parity bonds and refunding bonds.

Please see attached the most recent S&P, Moody's and Fitch credit reports for Dare County NC. Current financials, Budgets and Capital Improvement Plans for the past 5 years can be found at the following link:

https://www.darenc.com/departments/finance

Bond Counsel and Financial Advisor: Parker Poe Adams & Bernstein LLP serves as bond counsel to the County and as the Corporation's counsel, will draft all bond documents, and will provide a validity opinion and an opinion as to the treatment of the interest component of installment payments under the Contract under State and federal tax law. By submitting a proposal, the successful proposer waives any conflict of interest that Parker Poe Adams & Bernstein LLP's involvement in connection

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\*Preliminary, subject to change.

Description of Dare

County:

## **TERM SHEET**

	with the financing presents to such successful proposer. DEC Associates, Inc. serves as the County's financial advisor.
Acceptance of Proposals:	The County reserves the right to select the proposal that best meets the needs of the County, but the selection will be primarily on the lowest interest cost to the County. The County reserves the right to reject all proposals. Selection of any proposal is subject to approval thereof and approval of documentation by Board of County Commissioners which is expected to occur on April 16, 2018 and the North Carolina Local Government Commission which is expected to occur on June 5, 2018.
Investment Letter:	An investment letter will be required that will contain the customary representations from purchasers as to the status of the purchasers and other customary representations.
Transfer Restriction:	The Bonds will be non-transferable, except to a bank, insurance company or similar financial institution or any other entity approved by the Local Government Commission of North Carolina.



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REGARDING THE USE OF THIS CONFIDENTIAL PRIVATE PLACEMENT MEMORANDUM

THE INFORMATION AND EXPRESSIONS OF OPINION HEREIN ARE SUBJECT TO CHANGE WITHOUT NOTICE, AND NEITHER THE DELIVERY OF THIS CONFIDENTIAL PRIVATE PLACEMENT MEMORANDUM NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE ISSUER SINCE THE DATE HEREOF.

THE BONDS HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

IN MAKING AN INVESTMENT DECISION, INVESTORS MUST RELY ON THEIR OWN EXAMINATION OF THE ISSUER AND THE TERMS OF THE OFFERING, INCLUDING THE MERITS AND RISKS INVOLVED. THESE SECURITIES HAVE NOT BEEN RECOMMENDED BY ANY FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS DOCUMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

#### **Additional Information Respecting Documentation**

The attached document is being sent to you as a prospective purchaser or lender in connection with a private placement or loan opportunity identified by Piper Jaffray & Co. or its affiliate. Piper Jaffray & Co. and its affiliates have not independently verified the information contained herein or otherwise made any further investigation of the loan, the credit of the borrower and any obligor, the collateral and the loan terms. Neither Piper Jaffray & Co. nor any of its affiliates, partners, officers, agents, employees or representatives makes any representation or warranty, express or implied, as to the accuracy or completeness of such information. All references to financial information of the borrower, any obligor or the collateral shall not be considered as applicable for any period after the date they are referenced, unless expressly stated otherwise.

In addition to the attached document, you as prospective purchaser will be provided with or granted access to all of the available financial and other information requested and deemed by you to be necessary to enable you to make an independent and informed judgment with respect to the collateral, the borrower and any obligor and their credit and the desirability of purchasing an interest in the prospective financing. You as prospective purchaser agree to make a complete examination of all loan documents and approve of the form and content of the same prior to your funding and you agree that Piper Jaffray & Co. and its affiliates shall have no responsibility to perform and have not independently performed an examination of or approved the loan documents or any specific loan terms and shall not have any duty to inspect the collateral or the books and records of borrower or any obligor.

By accepting this package and considering becoming a prospective purchaser, you hereby represent that you have the sophistication and knowledge required to evaluate the loan, the credit of the borrower and any obligor, the collateral and the loan terms and that you will make your own independent credit analysis and decision to purchase your interest in the loan based upon your own independent examination and evaluation of the loan transaction and the information you have deemed appropriate, without reliance on Piper Jaffray & Co. or its affiliates, its directors, officers, employees, attorneys or agents.

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\*Preliminary, subject to change.

# Dare County Public Facilities Corporation Dare County, North Carolina Limited Obligation Bonds, Series 2018

#### **TERM SHEET**

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\*Preliminary, subject to change.



Interlocal Agreement among the COUNTY OF DARE, NORTH CAROLINA and the TOWN OF NAGS HEAD, NORTH CAROLINA

# Description

Attached is the Interlocal Agreement, drafted by bond counsel Parker Poe Adams & Bernstein, between the County and Nags Head for the 2019 beach nourishment maintenance project in Nags Head. All terms are per the funding approved by the Board for the project on May 1, 2017.

## **Board Action Requested**

Approve the Interlocal Agreement and authorize the Chairman to execute the same.

## **Item Presenter**

Bobby Outten, County Manager

## **INTERLOCAL AGREEMENT**

This INTERLOCAL AGREEMENT dated as of \_\_\_\_\_\_, 2018 (the "Interlocal Agreement") among the COUNTY OF DARE, NORTH CAROLINA, a political subdivision of the State of North Carolina (the "County") and the TOWN OF NAGS HEAD, NORTH CAROLINA, a municipal corporation organized under the laws of the State of North Carolina (the "Town");

#### WITNESSETH

*WHEREAS*, the Town has determined to undertake a beach nourishment project (the "*Project*") within the Town and the County as they are authorized to do under North Carolina law;

WHEREAS, the Town expects to enter into construction contracts for the Project in 2018;

*WHEREAS*, the County has determined to assist the Town in financing the beach nourishment project from the County's Beach Nourishment Fund and such other funds as the County may determine;

**WHEREAS**, under Article 20 of Chapter 160A of the North Carolina General Statutes, as amended (the "*Interlocal Act*"), municipalities and counties are authorized to enter into interlocal cooperation undertakings with other local governments for the joint exercise of any power, function, public enterprise, right, privilege, or immunity of local governments in North Carolina;

WHEREAS, the parties to this Interlocal Agreement desire to set forth their agreement herein;

*NOW THEREFORE*, the parties hereto agree as follows:

#### ARTICLE I STATEMENT OF PURPOSE

The Town and the County are entering into this Interlocal Agreement under the Interlocal Act to cooperate in the financing of the Project. This Interlocal Agreement sets forth the parties understanding as to the construction and financing of the Project.

#### ARTICLE II ADMINISTRATION OF PROJECT AND INTERLOCAL AGREEMENT

The Town will be solely responsible for the administration and construction of the Project. The County will assign a non-exclusive right in each beach nourishment easement which the County has obtained or received for properties located in the Project area. The Town will not knowingly violate the terms of such easements provided by the County.

The County Manager and the County Finance Director, individually or collectively, or their designees, will be responsible for administering this Interlocal Agreement for the County. The Town Manager and the Town Finance Director, individually or collectively, or their designees, will be responsible for administering this Interlocal Agreement for the Town.

#### ARTICLE III FINANCING OF PROJECT

Section 3.1. **Project Funding.** The Project is estimated to cost at least \$25,546,711. The Town will provide funding for \$12,773,355 of the costs of the Project, plus any increased cost, if applicable. The County will provide \$12,773,356 to support the costs of the Project as follows:

(a) The County will transfer from the County's Beach Nourishment Fund to the Town the amounts and in the years as follows to be used towards the payment of debt service of the Town's special obligation bonds issued to finance the Project:

Fiscal Year ending June 30	Amount
2019	\$600,000
2020	600,000
2021	600,000
2022	600,000
2023	600,000

The County will pay such amounts in each fiscal year on the 15<sup>th</sup> day of the month preceding the date of the principal payment due on the Town's special obligation bonds issued to finance the Project or such other date as the County and the Town may mutually agree.

(b) In addition to the funding to be provided by the County under Section 3.1(a), the County will finance \$9,773,356 to pay costs of the Project. The County will distribute money from its financing on request of the Town to pay costs of construction of the Project on a pro rata basis with funds provided by the Town to pay costs of construction of the Project.

Section 3.2. **Conditions to Funding.** Prior to the County providing any of the funding set forth in Section 3.1, the Town: (1) will receive all necessary federal, state and local permits or approvals necessary for the Project, (2) will receive North Carolina Local Government Commission approval of the Town's issuance of special obligation bonds to finance the Project, (3) will have arranged for the sale and issuance of the Town's special obligation bonds and (4) will have entered into a valid and enforceable construction contract for the Project with the Project's construction contractor. The County's funding set forth in Section 3.1(b) is subject to approval by the North Carolina Local Government Commission.

Section 3.3. *Cooperation in Financings.* The Town and the County will be assisted in its financing for the Project by Parker Poe Adams & Bernstein LLP, as bond counsel, and by DEC Associates Inc., as financial advisor. The Town and the County will cooperate in seeking the approval of the North Carolina Local Government Commission for the financings.

#### ARTICLE IV DISPUTES AND MEDIATION

Section 4.1. Agreement to Work Together to Settle Disputes. This Interlocal Agreement shall be liberally construed in order to promote a harmonious relationship between the parties with regard to the completion of the Project. The County and the Town accept the relationship of trust and confidence established between each of the parties by this Interlocal Agreement. If a problem or dispute arises that this Interlocal Agreement does not directly or indirectly address, the County and the Town covenant to work with one another in good faith to determine a mutually satisfactory solution.

## Section 4.2. *Mediation*.

a. Agreement to Mediate Dispute. The County and the Town will attempt to settle any dispute, claim or controversy arising out of this Interlocal Agreement through consultation and negotiation in good faith and in a spirit of mutual cooperation as set forth in Section 4.1. If those attempts fail, then the claim or dispute will be mediated by a mutually-acceptable mediator before any party resorts to court action. Mediation is a process in which parties attempt to resolve a dispute by submitting it to an impartial, neutral mediator who is authorized to facilitate the resolution of the dispute, but who is not empowered to impose a settlement on the parties.

b. *Demand for Mediation.* A demand for mediation must be submitted in writing to the other parties to this Interlocal Agreement. The demand for mediation shall proceed in advance of legal or equitable court proceedings, which shall be stayed pending mediation for a period of 60 days from the date of the demand for mediation, unless stayed for a longer period by agreement of the parties or by court order.

c. *Selection of Mediator.* The parties shall jointly select a mediator within 45 days after written notice by either party demanding mediation. The mediator shall be a member of the North Carolina State Bar and residing in the First Judicial District of North Carolina. Failing this joint action, the parties shall each separately designate a mediator and, within 15 days after their appointment, the two designated mediators shall jointly designate a third mediator. The third mediator shall then become the sole mediator for purposes of this paragraph. The failure of either party to appoint a mediator within the time allowed shall be deemed equivalent to appointing the mediator appointed by the other party. Each mediator shall be disinterested in the subject matter of this Interlocal Agreement.

d. *Mediation Procedure*. The mediation procedure shall be that which is contained in the Rules Implementing Statewide Mediated Settlement Conferences in Superior Court Civil Actions adopted pursuant to N.C. Gen. Stat. Sec. 7A-38.1 as same may be amended from time to time.

e. *Miscellaneous provisions.* 

(1) The mediation fee, if any, shall be divided equally among the parties

involved.

(2) Each party shall pay its own attorneys' fees and other costs.

(3) Before the mediation begins, the parties agree to sign a document limiting the admissibility in arbitration or any civil action of anything said, any admission made, and any documents prepared, in the course of the mediation.

(4) If any party commences a court action based on a dispute or claim to which this paragraph applies without first attempting to resolve the matter through mediation, then, in the discretion of the judge, that party shall not be entitled to recover attorney's fees even if they would otherwise be available to that party in any such court action. However, the filing of a judicial action to enable the recording of a notice of pending action, for order of attachment, receivership, injunction, or other provisional remedies, shall not in itself constitute a loss of the right to recover attorney's fees under this provision.

(5) The following matters are excluded from the requirement of mediation hereunder: interim relief from a court that a party reasonably believes is necessary to prevent serious and irreparable injury to one party or to others.

## ARTICLE V LIABILITIES AND INDEMNIFICATION

Except as otherwise provided under this Interlocal Agreement, any liabilities arising from the Project will be the sole responsibility of the Town. The Town will indemnify, protect and save the County and any member of the governing body, officer, agent or employee thereof, acting in such capacity, harmless from all liability, obligations, losses, claims, damages, actions, suits, proceedings, costs and expenses, including reasonable attorneys' fees, arising out of, connected with, or resulting, directly or indirectly, from any third party claim arising from the Project, or from injuries to person or property occurring from or related to the Project. The indemnification arising under this Article shall survive the termination of this Interlocal Agreement and continue in full force and effect notwithstanding the payment in full of all obligations under this Interlocal Agreement.

The County will indemnify, protect and save the Town and any member of the governing body, officer, agent or employee thereof, acting in such capacity, harmless from all liability, obligations, losses, claims, damages, actions, suits, proceedings, costs and expenses, including reasonable attorneys' fees, arising out of, connected with, or resulting, directly or indirectly from the failure of the County to provide the funding in accordance with the terms of this Interlocal Agreement. The indemnification arising under this Article shall survive the termination of this Interlocal Agreement and continue in full force and effect notwithstanding the payment in full of all obligations under this Interlocal Agreement.

#### ARTICLE VI PERFORMANCE OF GOVERNMENT FUNCTIONS

Nothing contained in this Interlocal Agreement shall be deemed or construed so as to in any way estop, limit, or impair the Town or the County from exercising or performing any regulatory, policing, legislative, governmental, or other powers or functions pursuant to applicable law.

#### ARTICLE VII DEFAULTS AND REMEDIES

The County and the Town will be in default under this Interlocal Agreement if it fails to comply with the terms of this Interlocal Agreement.

If an event of default occurs as set forth in the preceding paragraph, and after following the procedures and requirements of Article IV herein, each party hereto will have all remedies available at law or in equity to enforce any of the terms and provisions hereof, including, but not limited to, actions at

law for damages and equitable actions seeking injunctive relief (mandatory or prohibitory) to prevent the breach or threatened breach of any term or provision thereof or to enforce the performance of all terms and conditions of this Interlocal Agreement. All remedies are cumulative; the exercise of any one or more of them will not in any way alter or diminish the rights of the exercising party to any other remedy provided herein or at law or in equity. Action under this Interlocal Agreement will not be taken, however, until the non-defaulting party or parties gives the defaulting party or parties written notice of the event of default and a reasonable opportunity to cure the event of default.

#### ARTICLE VIII NOTICES

Except as otherwise provided in this Interlocal Agreement, all notices, certificates, requests, requisitions, or other communications given pursuant to this Interlocal Agreement must be in writing and will be sufficiently given and will be deemed given when delivered by hand or mailed by certified mail, postage prepaid, addressed as follows:

County:	Dare County Attention County Manager PO Box 1000 Manteo, NC 27954
Town:	Town of Nags Head

Attention Town Manager PO Box 99 Nags Head, NC 27959

## ARTICLE IX MISCELLANEOUS

Section 9.1. *Amendment.* This Interlocal Agreement may be amended through a supplement approved in writing by the County and the Town.

Section 9.2. *Severability.* If any section of this Interlocal Agreement is deemed to be illegal or otherwise unenforceable, it is the intent of the parties hereto that all other provisions of this Interlocal Agreement shall remain in full force and effect.

Section 9.3. *Governing Law.* This Interlocal Agreement is to be governed by and interpreted in accordance with the laws of the State of North Carolina.

Section 9.4. *Time is of the Essence*. Time is of the essence in this Interlocal Agreement.

Section 9.5. *Execution in Multiple Counterparts.* This Interlocal Agreement may be executed in multiple counterparts, each of which constitutes a completed document.

Section 9.6. *Effective Date.* This Interlocal Agreement takes effect on its execution by the County and the Town.

Section 9.7. *Termination.* This Interlocal Agreement shall terminate under either of the following two (2) circumstances: (1) all duties and responsibilities of the County and Town set forth in this Interlocal Agreement have been completed or waived in writing by the parties; or (2) the date on

which the County and Town mutually agree to terminate this Interlocal Agreement by action of their respective governing boards.

Section 9.8. *Public Information.* All public information related to the Project shall be the responsibility of the Town.

*IN WITNESS WHEREOF*, the Chairman of the Board of Commissioners of the County and the Mayor of the Town have each executed this Interlocal Agreement to evidence the agreement of the parties hereto.

#### **COUNTY OF DARE, NORTH CAROLINA**

By:\_\_\_

Chairman

Attest:

Clerk to the Board of County Commissioners

This instrument has been preaudited in the manner required by the Local Government Budget and Fiscal Control Act.

Finance Officer, County of Dare, North Carolina

TOWN OF NAGS HEAD, NORTH CAROLINA

By:

Mayor

Attest:

Town Clerk

This instrument has been preaudited in the manner required by the Local Government Budget and Fiscal Control Act.

Finance Officer Town of Nags Head, North Carolina



Resolution Requesting Funding of the Coastal Storm Damage Mitigation Fund

# Description

In 2017 the North Carolina Legislature included a provision in HB56 to create a Coastal Storm Damage Mitigation Fund that would be used for costs associated with beach nourishment, artificial dunes, and other projects to mitigate or remediate coastal storm damage. The special revenue fund would match local dollars on a cost-shared basis thus allowing beach nourishment funds to be effectively leveraged for maximum benefit. Although the Fund has been created, a funding source has not yet been allocated by the State.

Attached is a resolution requesting that the General Assembly vote in the upcoming short session to fund the Coastal Storm Damage Mitigation Fund as an urgent matter to safeguard the shoreline infrastructure that is vital to North Carolina's tourism economy and the tax revenue that it generates.

## **Board Action Requested**

Adopt Resolution

## **Item Presenter**

Chairman Robert Woodard



# RESOLUTION ASKING THE NORTH CAROLINA GENERAL ASSEMBLY TO FUND THE COASTAL STORM DAMAGE MITIGATION FUND

**WHEREAS**, North Carolina tourism represents an economic engine that is vital to North Carolina's future economic prosperity and generates State tax revenue that benefits all North Carolinians; and

**WHEREAS**, one of the cornerstones of North Carolina's tourism economy are its pristine beaches that attract visitors from around the world; and

**WHEREAS**, in order to sustain North Carolina's tourism economy and safeguard the tax revenue that it generates, it is imperative that the State's shorelines remain healthy, vibrant, and sustainable; and

**WHEREAS**, the shorelines of North Carolina are under constant threat of natural hazards and erosion, which has an adverse impact on wildlife, public infrastructure, and private property; and

**WHEREAS**, in recent years, federal funds for beach nourishment projects have decreased significantly forcing coastal communities, such as Dare County, to use local dollars to fund beach nourishment projects; and

**WHEREAS**, as more of the State's shoreline becomes vulnerable and in need of nourishment or re-nourishment, local dollars alone are unable to fund the amount that is needed to sustain and preserve North Carolina's beaches and safeguard the benefit that coastal tourism contributes to the State's economy; and

**WHEREAS**, multiple areas in our coastal communities have undergone significant beach erosion in recent years that cannot be sufficiently addressed with local resources alone; and

**WHEREAS**, the North Carolina Legislature in 2017 had the foresight to include in HB56 a provision to create a Coastal Storm Damage Mitigation Fund that would be used for costs associated with beach nourishment, artificial dunes, and other projects to mitigate or remediate coastal storm damage; and

**WHEREAS**, the Coastal Storm Damage Mitigation Fund would match local dollars on a cost-shared basis thus allowing local beach nourishment funds to be effectively leveraged for maximum benefit; and

**WHEREAS**, although the Coastal Storm Damage Mitigation Fund has been created, a funding source has not yet been allocated by the State to provide the infrastructure benefit that the General Assembly intended in establishing the special revenue fund.

**NOW THEREFORE BE IT RESOLVED** that the Dare County Board of Commissioners respectfully requests that the North Carolina General Assembly vote in the upcoming short session to fund the Coastal Storm Damage Mitigation Fund as an urgent matter of public importance to safeguard and protect the shoreline infrastructure that fuels the engine of North Carolina's tourism economy.

Adopted this the 7<sup>th</sup> day of May, 2018.

Robert Woodard, Chairman

ATTEST:

Gary Lee Gross, Clerk to the Board



Letter of Support for Town of Kitty Hawk Grant Application

# Description

The Town of Kitty Hawk requests a letter of support for their application to acquire grant funding from the North Carolina Division of Parks & Recreation for two trail connections to the existing 1.8 mile Birch Lane Trail located in the Kitty Hawk Woods Preserve.

Attached is a letter of support outlining the benefits of the proposed connector trails.

## **Board Action Requested**

Approve a letter of support to be signed by the Chairman

## **Item Presenter**

Robert Outten, County Manager



# **County of Dare**

Office of the Board of Commissioners P.O. Box 1000 | Manteo, North Carolina 27954 | 252.475.5700 Robert Woodard Chairman

Wally Overman Vice Chairman

> Jack Shea Steve House Rob Ross Jim Tobin Danny Couch

Robert L. Outten County Manager / Attorney

> Gary Lee Gross Clerk to the Board

May 7, 2018

North Carolina Division of Parks and Recreation 1212 W. Jones Street Raleigh, NC 27669

To Division of Parks and Recreation:

This letter is in support of the Town of Kitty Hawk's effort to acquire grant funding under the Division of Parks & Recreation Trails Program for two trail connections to the existing 1.8 mile Birch Lane Trail located in the Kitty Hawk Woods Preserve.

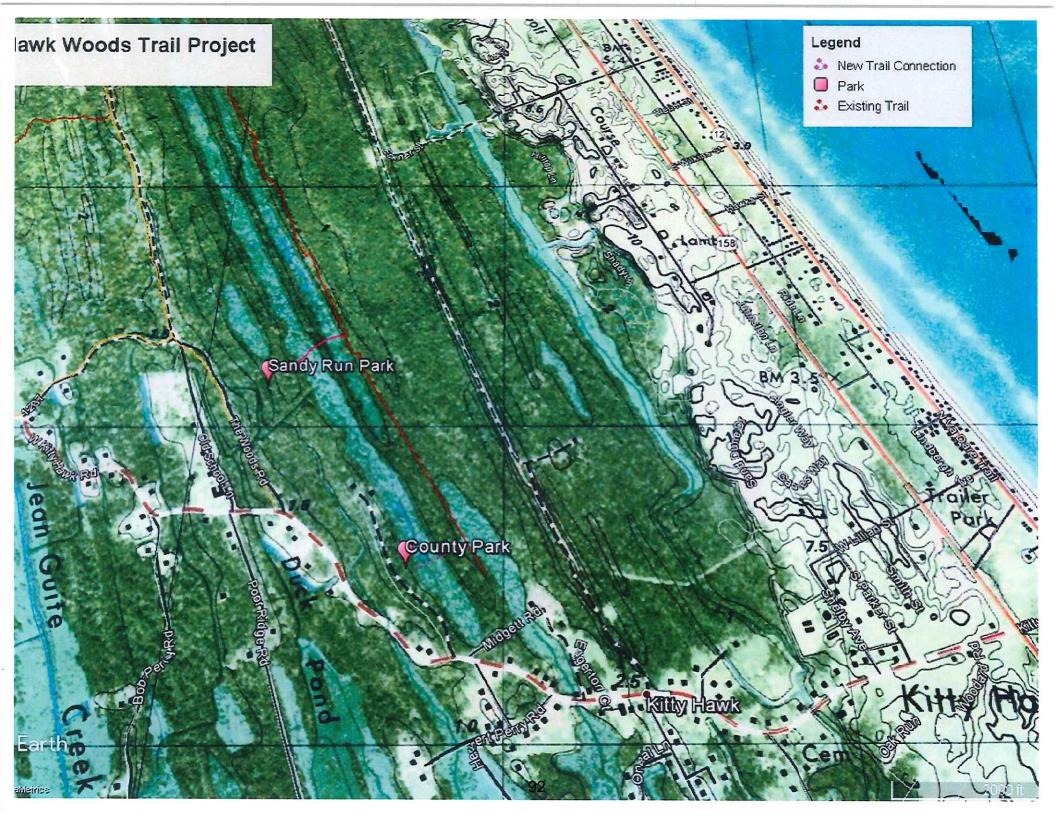
The connector trails being proposed by the Town would ultimately provide connectivity between the Town owned Sandy Run Park and the Dare County Park referred to as "Kitty Hawk Park". The proposed connection would provide pedestrian access to the Kitty Hawk Woods Preserve which is currently limited at Kitty Hawk Park. The Kitty Hawk Park currently features a skate park, dog park, picnic, and restroom facilities.

In addition, the construction of two connector trails as presented by the Town of Kitty Hawk to the Birch Lane Trail would provide for the opportunity for both the Town and County to share resources available at both Parks. Both Parks are highly utilized on a daily basis and this project would expand the recreational opportunities available for residents and visitors in the Town of Kitty Hawk.

It is with great pleasure to submit this letter of support for consideration of grant funding for the proposed trail connection.

Sincerely,

Robert L. "Bob" Woodard, Sr., Chairman Dare County Board of Commissioners





NCDOT Right of Way and Utility Easement

# Description

NCDOT seeks to acquire a Right of Way and Utility Easement on County owned property on Colington Road (SR 1217).

The Right of Way involves 0.058 acre with a value of \$2,575. The Utility Easement consists of 0.045 acre at a value of \$1800. The total offer from NCDOT is \$4,375 and the Dare County Tax Office confirms the values.

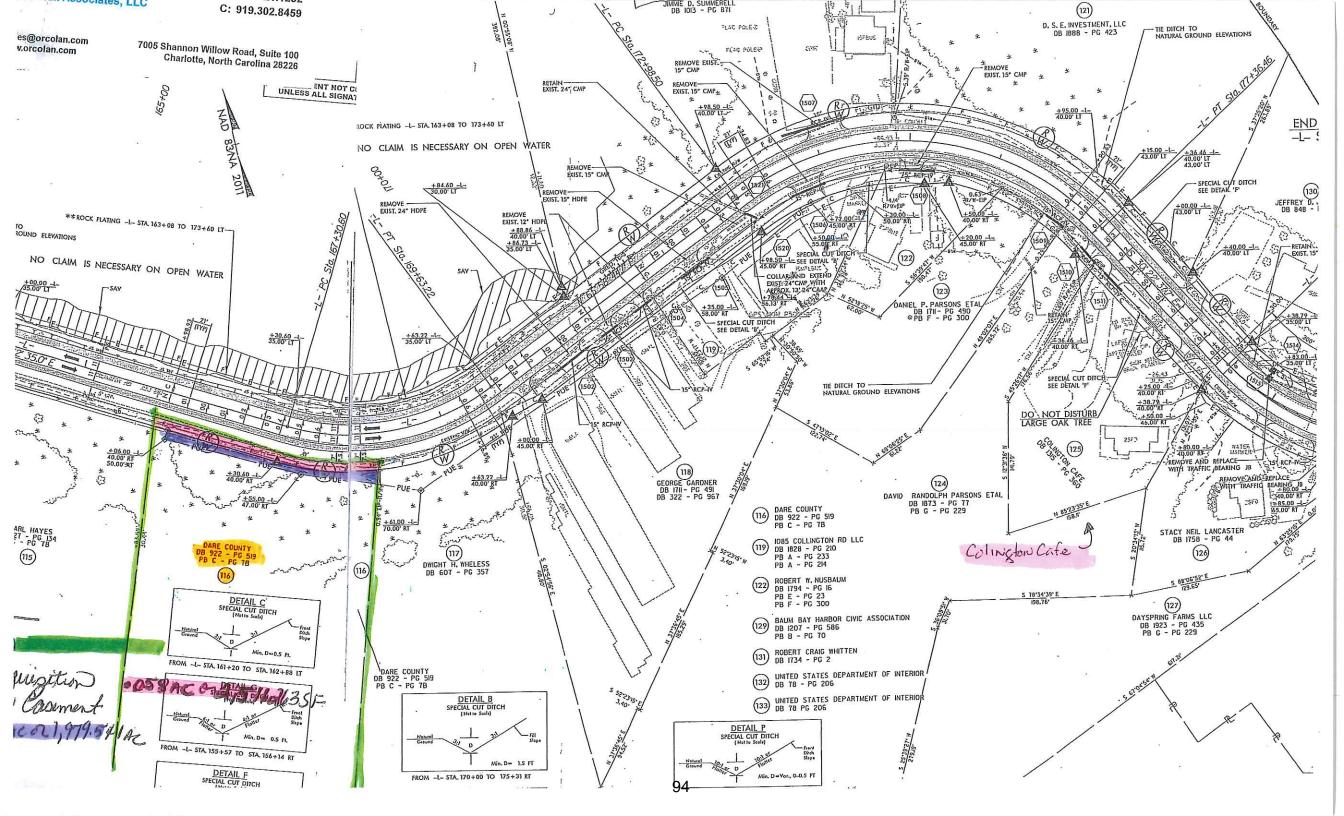
The enclosed map shows the Right of Way highlighted in pink and the Utility Easement highlighted in purple. Also enclosed is an NCDOT Right of Way Claim Report, Offer to Purchase Real Property, and a Right of Way Deed.

# **Board Action Requested**

Approve the Right of Way and Utility Easement and authorize the Manager to sign all necessary documents.

## **Item Presenter**

Robert Outten, County Manager



# **RIGHT OF WAY CLAIM REPORT**

TIP/PARCEL # R-5014	116	V	/BS		41162.2	2.1			COUNTY		Ε	Dare
CLAIM OF Dare County									PLAN SHEET			14-15
1 Land Area to be Acquire	d (Paymen	t per acre si	upp	orteo	d by recent l	and	d sales	on	file.)			*
RIGHT OF WAY	R/W	0.058 AC	х	\$	44,000.00	х	100%	=	2,552.00	0	\$	2,575.00
PERM Drainage Easement	PDE	AC	х	\$	-	Х	90%		0.00		<u>+</u>	
PERM Utility Easement	PUE	0.045 AC	х	\$	44,000.00	x	90%	-	1,782.00			
PERM Drainage/Utility Easement	DUE	AC	х	\$	-	х	90%		0.00			
PERM Aerial Utility Easement	AUE	AC	х	\$	-	х	90%	=	0.00			
PERM Construction Easement	PCE	AC	х	\$	-	х	90%	=	0.00			
PERM OTHER	OTH	AC	х	\$	-	х	90%	=	0.00			
<									PERM TOTAL	@	\$	1,800.00
TEMP Construction Easement	TCE	AC	х			х	20%	=	0.00			
TEMP Drainage Easement	TDE	AC	х	\$	-	x	20%	=	0.00			
TEMP Utility Easement	TUE	AC	х	\$	-	x	20%	=	0.00			
TEMP OTHER	OTH	AC	х	\$		х	20%	=	0.00			
								be-	TEMP TOTAL	®	\$	-
									LAND TOTAL		\$	4,375.00
2 Payment for improvement(s n/a	) to be acqu	ired. Materia	al an	d lab	oor cost docu	mer	nted in t	he S	State's files. \$ \$			
					The second s				<u>\$</u> -			
							IMPI	ROV	EMENTS TOTAL	_	\$	
3 Cost to cure (Damage to Render n/a	emainder)								\$ -			
						-		TZC	TO CURE TOTAL	-	\$	
								51	TO CORE TOTAL		ې	-
Comments		· · · ·							GRAND TOTAL	_	\$	4,375.00
Values provided by project ap	nraiser								1			
	praiser.				*							
Cortificate of Property and Appr	wor I horok	w portify that	Lor	a fan	ailian with the		in a mhu u u	hiele	is the subject of f	le fee		
Certificate of Preparer and Appro estimate; that this estimate is ba present or contemplated future p	sed on data	contained in	the	files	of the agency	/ an	d that I	hav	e no direct or indi	rect	,	
If the total of this estimate is o negotiating agent and (2) the c	ver \$10,000	, (1) this est	ima	te m	ust be prepa	red	l by sor	nec	ne other than th	e	•	
Preparer Signature:		Jan	7		lace -				Dat	۵	12/	21/2017
	*_	Joe	Mar	in					Dat	٠ <u> </u>	14/	
NODOTA			-	. 2					_			
NCDOT Approval Signature:	~ ~ ~ )	i constant Mic			Pittman	<u> </u>		nan na	Dat	e	1/:	10/2018
TEMPORARY EASEMENT TOTAL	\$	-			PI	ERN	/IANEN1	ΓEA	SEMENT TOTAL		\$	1,800.00
FRM4-N REVISED 03/03/2017												

# SUMMARY STATEMENT/CONTINGENT OFFER TO PURCHASE REAL PROPERTY DUE TO THE ACQUISITION OF RIGHT OF WAY AND DAMAGES

TO:	Dare County	,	DATE: 21/6/18
	2601 Virginia	a Dare Trail	TO: Lessee, if Applicable
	Manteo, NC	27954	N/A
TIP/P	ARCEL NO .:	R-5014 116	
COU	YTY	Dare	WBS ELEMENT: 41162.2.1
DESC	CRIPTION:	SR 1217 (Colington Road	I) from Dead End to US 158 (Croatan Hwy) in Kill Devil Hills

Dear Property Owner:

The following contingent offer of just compensation is based on the fair market value of the property and is not less than the approved appraised value for the appropriate legal compensable interest or interests. The approved value disregards any increase or decrease in the fair market value of the property acquired due to influence caused by public knowledge of this project. The contingent offer of just compensation is based on an analysis of market data, comparable land sales, and, if applicable, building costs in the area of your property. **Please retain this form as it contains pertinent income tax information.** 

TOTAL CONTINGENT OFFER		\$_4,375.00
Benefits, if any, to Remainder	minus	\$ <u>N/A</u>
Damages, if any, to Remainder		\$_N/A
Value of Improvements to be Acquired		\$_N/A
Value of Temporary Easement (Rental of Land) to be Acqu	ired	\$ <u>N/A</u>
Value of Permanent Easements to be Acquired		\$
Value of Right of Way to be Acquired		\$

The total contingent offer includes all interests other than leases involving Federal Agencies and Tenant owned improvements.

(A) Description of the land and effects of the acquisition

Subject property described in Deed Book 0922, page 0519, Dare County Registry, contains approximately 6.240 acres of which 0.058 acres is being acquired as right of way, leaving 6.182 acres remaining on the right with access to SR 1217 Colington Road. Also, being acquired is a permanent utility easement containing approximately 0.045 acres.

(B) The TOTAL CONTINGENT OFFER includes payment for the improvements and appurtenances described below: None

Provided there is sufficient time remaining in the project schedule, you may repurchase these improvements for a retention value, with the stipulation that you remove them from the acquisition area at no expense to the Department.

(C) Should you desire to sell the Department the portion of your property considered to be an uneconomic remnant or buildable lot, as explained to you by the Right of Way Agent, the total contingent offer would be: <u>N/A</u> Please note that any contingent offer to purchase a remnant/buildable lot is conditioned upon the remnant/buildable lot being environmentally clean prior to the conveyance to the Department. You may be required to provide the Department with a release from the appropriate environmental agency stating that all contaminants have been remediated and/or removed to their standards.

The original of this form was handed/mailed,	if out of state owner, to	Mr. Robert Outten
on	2/16	20 18 . Owner was furnished a copy of
the Right of Way Brochure/Owner's Letter.		

I will be available at your convenience to discuss this matter further with you. My telephone number is (252) 621-1232

Please be advised that the agent signing this form is only authorized to recommend settlement to the North Carolina Department of Transportation, and any recommended settlement is not a binding contract unless and until accepted by the North Carolina Department of Transportation by its formal execution of documents for conveyance of Right of Way, Easements, and/or other interests.

(Sianed

FRM10-B Revised 2/17/15

Revenue Stamps \$ DEED FOR HIGHWAY RIGHT OF WAY
THIS INSTRUMENT DRAWN BY Tinnette Hales Gist CHECKED BY Michelle A. Pittman
The hereinafter described property 🔲 Does 🖾 Does not include the primary residence of the Grantor
RETURN TO: Division R/W Agent, NCDOT
NORTH CAROLINA TIP/PARCEL NUMBER: R-5014 116
COUNTY OF         Dare         WBS ELEMENT:         41162.2.1           TAX PARCEL         026695000         ROUTE:         SR 1217
THIS FEE SIMPLE DEED, made and entered into this the day of 2018         by and between
hereinafter referred to as GRANTORS, and the Department of Transportation, an agency of the State of North Carolina, 1546 Mail Service Center, Raleigh, NC 27611, hereinafter referred to as the Department;
WITNESSETH
That the GRANTORS, for themselves, their heirs, successors, and assigns, for and in consideration of the sum of \$ agreed to be paid by the DEPARTMENT to the GRANTORS, do hereby give, grant and convey unto the DEPARTMENT, its successors and assigns, in FEE SIMPLE that certain property located in Atlantic Township, Dare County, North Carolina, which is particularly described as follows:
Point of beginning being S 52^58'10.0" E, 140.439 feet from -L- Sta 167+00 thence to a point on a bearing of N 16^20'46.6" E 8.778 feet thence to a point on a bearing of N 16^20'46.6" E 0.936 feet thence along a curve 58.852 feet and having a radius of 259.183 feet. The chord of said curve being on a bearing of N 76^35'23.1" W, a distance of 58.726 feet thence along a curve 79.903 feet and having a radius of 484.184 feet. The chord of said curve being on a bearing of N 63^55'48.2" W, a distance of 79.812 feet thence to a point on a bearing of N 60^42'35.0" W 112.083 feet thence to a point on a bearing of S 19^33'38.6" W 10.146 feet thence to a point on a bearing of S 60^42'35.0" E 15.556 feet thence to a point on a bearing of S 60^42'35.0" E 124.602 feet thence along a curve 111.268 feet and having a radius of 290.000 feet. The chord of said curve being on a bearing of S 71^42'5.2" E, a distance of 110.587 feet returning to the point and place of beginning.
FRM7-A Page 1 of 3 Revised 02/17/15

COUNTY:	Dare	WBS ELEMENT:	41162.2.1	TIP/PARCEL NO.:	R-5014 116

IN ADDITION, and for the aforestated consideration, the GRANTORS further hereby convey to the DEPARTMENT, its successors and assigns the following described areas and interests:

#### Permanent Utility Easement described as follows:

Point of beginning being S 52^58'10.0" E, 140.439 feet from -L- Sta 167+00 thence along a curve 111.268 feet and having a radius of 290.000 feet. The chord of said curve being on a bearing of N 71^42'5.2" W, a distance of 110.587 feet thence to a point on a bearing of N 60^42'35.0" W 124.602 feet thence to a point on a bearing of S 29^17'25.0" W 10.000 feet thence to a point on a bearing of S 62^21'22.1" E 153.604 feet thence to a point on a bearing of S 62^21'22.1" E 153.604 feet thence to a point on a bearing of S 68^37'20.5" E 83.893 feet thence to a point on a bearing of N 16^20'46.6" E 15.517 feet returning to the point and place of beginning. Having an area of 1979.541 Sqr feet being 0.045 acres.

Said Permanent Utility Easement in perpetuity is for the installation and maintenance of utilities, and for all purposes for which the DEPARTMENT is authorized by law to subject same. The Department and its agents or assigns shall have the right to construct and maintain in a proper manner in, upon and through said premises utility line or lines with all necessary pipes, poles and appurtenances, together with the right at all times to enter said premises for the purpose of inspecting said utility lines and making all necessary repairs and alterations thereon; together with the right to cut away and keep clear of said utility lines, all trees and other obstructions that may in any way endanger or interfere with the proper maintenance and operation of the same with the right at all times of ingress, egress and regress. The underlying fee owner shall have the right to continue to use the Permanent Utility Easement area(s) in any manner and for any purpose, including but not limited to the use of said area for access, ingress, egress, and parking, that does not, in the determination of the Department, obstruct or materially impair the actual use of the easement area(s) by the Department of Transportation, its agents, assigns, and contractors.

SPECIAL PROVISIONS. This deed is subject to the following provisions only:

None

The property hereinabove described was acquired by the GRANTORS by instrument(s) recorded in the Dare County Registry in Deed Book 0922 Page 0519

The final right of way plans showing the above described right of way are to be certified and recorded in the Office of the Register of Deeds for said County pursuant to N.C.G.S. 136-19.4, reference to which plans is hereby made for purposes of further description and for greater certainty.

The Grantors acknowledge that the project plans for Project # 41162.2.1 have been made available to them. The Grantors further acknowledge that the consideration stated herein is full and just compensation pursuant to Article 9, Chapter 136 of the North Carolina General Statutes for the acquisition of the said interests and areas by the Department of Transportation and for any and all damages to the value of their remaining property; for any and all claims for interest and costs; for any and all damages caused by the acquisition for the construction of Department of Transportation Project # 41162.2.1

Dare County, and for the past and future use of said areas by the Department of Transportation, its successors and assigns for all purposes for which the said Department is authorized by law to subject the same.

TO HAVE AND TO HOLD the aforesaid premises and all privileges and appurtenances thereunto belonging to the DEPARTMENT, its successors and assigns in FEE SIMPLE, or by easement as indicated, for the past, present and future use thereof and for all purposes which the said Department is authorized by law to subject the same.

And the GRANTORS covenant with the DEPARTMENT, that the GRANTORS are seized of the premises in fee simple, have the right to convey the same in fee simple, or by easement as indicated, that the title thereto is marketable and free and clear of all encumbrances, and that the GRANTORS will warrant and defend the title against the lawful claims of all persons whomsoever except for the exceptions hereinafter stated. Title to the property hereinabove described is hereby conveyed subject to the following exceptions: None

IN WITNESS WHEREOF, the GRANTORS have hereunto set their hands and seals (or if corporate, has caused the instrument to be signed in its corporate name by its duly authorized officers and its seal to be hereunto affixed by authority of its Board of Directors) the day and year first above written.

This instrument does not transfer the herein described interests unless and until this document is accepted by an authorized agent of the Department of Transportation.

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COUNTY:	Dare	WBS ELEMENT:	41162.2.1	TIP/PARCEL NO.:	R-5014 116
		(SEAL)		····	(SEAL)
		(SEAL)			(SEAL)
BY:					

(President)

# ACCEPTED FOR THE DEPARTMENT OF TRANSPORTATION BY:

	North Carolina, County
	I,, a Notary Public for County, North Carolina, do hereby certify that
	personally appeared before me this day and acknowledged the due execution of the foregoing instrument. Witness my hand and official seal this the day of , 20
	Notary Public
jā ieksa dabal	My commission expires:
	North Carolina, County
	I,, a Notary Public for
	County, North Carolina, do hereby certify that personally came
	before me this day and acknowledged that he/she is president of
	, a corporation, and that he/she,
	as president, being authorized to do so, executed the foregoing on behalf of the corporation.
	Witness my hand and official seal this the day of , 20
	Notary Public
li taran dering	My commission expires:

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Civil Complaint Seeking Remedies Against Those Responsible for the Opioid Crisis

# Description

On April 3, 2018 the Dare County Board of Commissioners voted unanimously to declare the opioid crisis as a public nuisance and to approve a representation agreement on a contingent fee basis with a consortium of law firms to pursue civil remedies against those responsible for the opioid crisis.

Attached is a draft civil complaint prepared by counsel representing Dare County.

## **Board Action Requested**

Discuss and take appropriate action

## **Item Presenter**

Robert Outten, County Manager

# IN THE UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NORTH CAROLINA NORTHERN DIVISION

DARE COUNTY,	
) Plaintiff, ) )	
v. )	CIVIL ACTION NO.
AMERISOURCEBERGEN DRUG)CORPORATION; CARDINAL HEALTH,)INC.; McKESSON CORPORATION;)PURDUE PHARMA L.P.; PURDUE)PHARMA, INC.; THE PURDUE FREDERICK)COMPANY, INC.; TEVA)PHARMACEUTICAL INDUSTRIES, LTD.;)TEVA PHARMACEUTICALS USA, INC.;)CEPHALON, INC.; JOHNSON & JOHNSON;)JANSSEN PHARMACEUTICALS, INC.;)ORTHO-MCNEIL-JANSSEN)PHARMACEUTICALS, INC. n/k/a JANSSEN)PHARMACEUTICALS, INC.; JANSSEN)PHARMACEUTICALS, INC.; NORAMCO,)INC.; ENDO HEALTH SOLUTIONS INC.;)ENDO PHARMACEUTICALS, INC.; NORAMCO,)INC.; ENDO HEALTH SOLUTIONS INC.;)ALLERGAN PLC f/k/a ACTAVIS PLC;)WATSON PHARMACEUTICALS, INC. n/k/a)ACTAVIS, INC.; WATSON)LABORATORIES, INC.; ACTAVIS LLC;)ACTAVIS PHARMA, INC. f/k/a WATSON)PHARMA, INC.;)MALLINCKRODT PLC and)MALLINCKRODT LLC.)	Complaint for Public Nuisance; Violations of Racketeer Influenced and Corrupt Organizations Act (RICO) 18 U.S.C. § 1961 <i>et seq.</i> ; Negligence and Negligent Misrepresentation; Negligence Per Se; Violation of North Carolina Unfair and Deceptive Trade Practices Act (UDTPA), N.C. Gen. Stat. 75-1.1, <i>et seq.</i> ; Civil Conspiracy; and Fraud and Fraudulent Misrepresentation
) ) )	JURY TRIAL DEMANDED AND ENDORSED HEREON

)

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Plaintiff, DARE COUNTY ("Plaintiff"), brings this Complaint against Defendants Purdue Pharma L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceutical Industries, LTD.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Johnson & Johnson; Janssen Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/aPharmaceuticals. Inc.: Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.; Noramco, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan PLC f/k/a Actavis PLS; Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc.; Watson Laboratories, Inc.; Actavis, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; McKesson Corporation; Cardinal Health, Inc.; and AmerisourceBergen Drug Corporation (collectively "Defendants") and alleges as follows:

## I. INTRODUCTION

1. Plaintiff brings this civil action to eliminate the hazard to public health and safety caused by the opioid epidemic, to abate the nuisance caused thereby and to recoup monies spent because of Defendants' false, deceptive and unfair marketing and/or unlawful diversion of prescription opioids.<sup>1</sup> Such economic damages were foreseeable to Defendants and were sustained because of Defendants' intentional and/or unlawful actions and omissions.

2. Opioid analgesics are widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.<sup>2</sup>

3. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> As used herein, the term "opioid" refers to the entire family of opiate drugs including natural, synthetic and semisynthetic opiates.

<sup>&</sup>lt;sup>2</sup> See Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies, 374 N. Eng. J. Med. 1253 (2016).

<sup>&</sup>lt;sup>3</sup> See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

4. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids and turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

5. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates.

#### II. <u>PARTIES</u>

## A. PLAINTIFF, DARE COUNTY.

6. Plaintiff is a county organized under North Carolina law. N.C. Gen. Stat. § 153A-1 *et seq.* The inhabitants of Dare County are a body politic and corporate under its name and "are vested with all the property and rights of property belonging to the corporation; have perpetual succession; may sue and be sued; may contract and be contracted; ... and have and may exercise in conformity with the laws of this State county powers, rights, duties, functions, privileges, and immunities of every name and nature." N.C. Gen. Stat. § 153A-11. Plaintiff is authorized by law to abate any nuisance that is dangerous or prejudicial to the public's health and safety and to prosecute in any court of competent jurisdiction any person who creates, continues, contributes to, or suffers such nuisance to exist and prevent injury and annoyance from such nuisance. N.C. Gen. Stat. § 153A-140. Further, to the extent North Carolina law grants standing for certain causes of action to "persons", such standing is also granted to Dare County. *See* N.C. Gen. Stat. § 12-3 (6) ("persons" as used in North Carolina statutory law includes "bodies . . . corporate"). Accordingly, pursuant to North Carolina law, Dare County has standing to bring this suit. *Id.*; N.C. Gen. Stat. § 153A-11, *supra*.

7. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity and mortality have created a serious public health and safety crisis, and are a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance. The Dare County Board of Commissioners has passed a resolution declaring the opioid crisis a public nuisance that must be abated for the benefit of Dare County and its residents and citizens.

8. The distribution and diversion of opioids into North Carolina ("the State"), and into Dare County and surrounding areas (collectively, "Plaintiff's Community"), created the foreseeable opioid crisis and opioid public nuisance for which Plaintiff here seeks relief.

9. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which the Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) 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; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs associated with law enforcement, with public safety relating to the opioid epidemic; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. The Plaintiff has suffered, and continues to suffer directly, these damages.

10. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

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11. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring actions as a corporation and a "person," including, *inter alia*; standing to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing).

12. Plaintiff seeks damages for economic losses and does not bring an action for personal injury, death, or physical injury to property.

#### **B. DEFENDANTS.**

#### 1. Manufacturer Defendants.

13. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

14. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

15. Purdue manufactures, promotes, sells and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER and Targiniq ER in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual nationwide sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from its 2006

4

sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

16. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a Delaware corporation registered to do business in North Carolina and is a wholly-owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

17. Cephalon, Inc. manufactures, promotes, sells and distributes opioids, such as Actiq and Fentora, in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."<sup>4</sup> Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."<sup>5</sup> In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425 million.<sup>6</sup>

18. Teva Ltd., Teva USA and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for

<sup>&</sup>lt;sup>4</sup> Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda\_docs/label/2009/020747s030lbl.pdf.

<sup>&</sup>lt;sup>5</sup> *Highlights of Prescribing Information, FENTORA*® (*fentanyl citrate*) *buccal tablet, CII* (2011), https://www.accessdata.fda.gov/drugsatfda\_docs/label/2012/021947s015lbl.pdf.

<sup>&</sup>lt;sup>6</sup> Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008),

https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that Teva USA submitted the guide, and directs physicians to contact Teva USA to report adverse events.

19. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.<sup>7</sup> Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including, *inter alia*, sales of Fentora®.<sup>8</sup> Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc. and Cephalon, Inc., are referred to as "Cephalon."

20. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in

<sup>&</sup>lt;sup>7</sup> E.g., ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left) (last visited Aug. 21, 2017).

<sup>&</sup>lt;sup>8</sup> Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ\_TEVA\_2012.pdf.

New Brunswick, New Jersey. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation registered to do business in North Carolina with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and J&J corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc.; Noramco and J&J are referred to as "Janssen."

21. Janssen manufactures, promotes, sells and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least \$1 billion in annual sales. Until January 2015, Janssen developed, marketed and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

22. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation registered to do business in North Carolina with its principal place of business in Malvern, Pennsylvania. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo."

23. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydone, in the United States. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER yielded \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

24 ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired ALLERGAN PLC in March 2015, and the combined company changed its name to ALLERGAN PLC in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ACTAVIS, INC. as of January 2013 and then ACTAVIS PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is registered to do business with the North Carolina Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. ALLERGAN PLC; ACTAVIS PLC; ACTAVIS, INC.; ACTAVIS LLC; ACTAVIS PHARMA,

INC.; WATSON PHARMACEUTICALS, INC.; WATSON PHARMA, INC. and WATSON LABORATORIES, INC. are referred to as "Actavis."

25. Actavis manufactures, promotes, sells and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008 and began marketing Kadian in 2009.

26. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in North Carolina. Mallinckrodt, LLC is a wholly owned subsidiary of MALLINCKRODT, PLC. MALLINCKRODT, PLC and MALLINCKRODT, LLC are referred to as "Mallinckrodt."

27. Mallinckrodt manufactures, markets and sells drugs in the United States, including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

#### 2. Distributor Defendants.

28. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges

the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

29. Defendant, McKESSON CORPORATION, is registered with the North Carolina Secretary of State as a Delaware corporation, which may be served through its registered agent for service of process, Corporation Service Company, 2626 Glenwood Avenue, Suite 550, Raleigh, North Carolina 27608. McKesson has its principal place of business located in San Francisco, California.

30. Defendant, CARDINAL HEALTH, INC., is an Ohio corporation with its principal office located in Dublin, Ohio and may be served through its registered agent for service of process, CT Corporation System, 4400 Easton Commons Way, Suite 125, Columbus, Ohio 43219. Cardinal Health, Inc. operates a distribution center in Greensboro, North Carolina.

31. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is registered with the North Carolina Secretary of State as a Delaware corporation, which may be served through its registered agent for service of process, CT Corporation System, 160 Mine Lake Court, Suite 200 Raleigh, N.C. 27615. AmerisourceBergen Drug Corporation's principal place of business is located in Chesterbrook, Pennsylvania.

32. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA<sup>9</sup> nor the wholesale distributors<sup>10</sup> will

<sup>&</sup>lt;sup>9</sup> See Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

<sup>&</sup>lt;sup>10</sup> See Declaration of Tina Lantz, Cardinal Health VP of Sales Operations, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.

33. Consequently, Plaintiff has named the three (3) wholesale distributors (i.e., AmerisourceBergen Drug Corporation; Cardinal Health, Inc. and McKesson Corporation) that dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. See Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc.; McKesson Corporation and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiff has reason to believe each has engaged in unlawful conduct that resulted in the diversion of prescription opioids into our community and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiff names each of the "Big 3" herein as defendants and places the industry on notice that the Plaintiff is acting to abate the public nuisance plaguing the community. Plaintiff will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

#### III. JURISDICTION & VENUE

34. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

35. This Court has personal jurisdiction over Defendants because they conduct business in North Carolina, purposefully direct or directed their actions toward North Carolina, consented to be sued in North Carolina by registering an agent for service of process, and/or consensually submitted to the jurisdiction of North Carolina when obtaining a manufacturer or distributor license and have the requisite minimum contacts with North Carolina necessary to constitutionally permit the Court to exercise jurisdiction.

36. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998) (citing *LaSalle National Bank v. Arroyo Office Plaza, Ltd.*, 1988 WL 23824, \*3 (N.D. Ill. Mar 10, 1988); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

37. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. §§ 1391(b); § 1965(a).

38. Plaintiff does not bring any product liability claims or causes of action and does not seek compensatory damages for death, physical injury to person or emotional distress. Claimant does not bring common law claims for physical property damage.

## IV. FACTUAL BACKGROUND

### A. THE OPIOID EPIDEMIC.

## 1. The National Opioid Epidemic.

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39. Increasing abuse and diversion of prescription drugs, including opioid medications,

have characterized the past two decades in the United States.<sup>11</sup>

40. Prescription opioids have become widely prescribed. By 2010, enough prescription

opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.<sup>12</sup>

41. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease

Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The

News Release noted:

a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.

b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin) and oxymorphone (Opana).

c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.

d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people reported using prescription painkillers non-medically, according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.

e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.

<sup>&</sup>lt;sup>11</sup> See Richard C. Dart et al, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).

<sup>&</sup>lt;sup>12</sup> Katherine M. Keyes et al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).

f. Almost 5,500 people start to misuse prescription painkillers every day.<sup>13</sup>

42. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population.<sup>14</sup>

43. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.<sup>15</sup>

44. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.<sup>16</sup>

45. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.<sup>17</sup>

<sup>&</sup>lt;sup>13</sup> See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011),

 $https://www.cdc.gov/media/releases/2011/p1101\_flu\_pain\_killer\_overdose.html.$ 

<sup>&</sup>lt;sup>14</sup> See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

<sup>&</sup>lt;sup>15</sup> See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health\_policy/monthly-drug-overdose-death-estimates.pdf.

<sup>&</sup>lt;sup>16</sup> See Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

<sup>&</sup>lt;sup>17</sup> See Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

46. The CDC reports that drug overdose deaths involving heroin continued to climb sharply, with heroin overdoses more than tripling in 4 years. This increase mirrors large increases in heroin use across the country and has been shown to be closely tied to opioid pain reliever misuse and dependence. *Past misuse of prescription opioids is the strongest risk factor for heroin initiation and use,* specifically among persons who report past-year dependence or abuse. The increased availability of heroin, combined with its relatively low price (compared with diverted prescription opioids) and high purity appear to be major drivers of the upward trend in heroin use and overdose.<sup>18</sup>

47. The societal costs of prescription drug abuse are "huge."<sup>19</sup>

48. Across the nation, local governments are struggling with a pernicious, everexpanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.<sup>20</sup>

49. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."<sup>21</sup> The

<sup>&</sup>lt;sup>18</sup> See Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014*, 64 Morbidity & Mortality Wkly. Rep. 1378 (2016).

<sup>&</sup>lt;sup>19</sup> See Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at \*10 [hereinafter Brief of HDMA].

<sup>&</sup>lt;sup>20</sup> Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugsabuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, <u>Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015</u>, *MMWR MORB MORTAL WKLY REP.* 2016;65, doi:10.15585/mmwr.mm655051e1).

<sup>&</sup>lt;sup>21</sup> Opioid Crisis, NIH.

economic burden of prescription opioid misuse alone is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.<sup>22</sup>

50. The U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.<sup>23</sup>

51. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.<sup>24</sup>

52. Every day brings a new revelation regarding the depth of the opioid plague: just to name one example, the New York Times reported in September 2017 that the epidemic, which now claims 60,000 lives a year, is now killing babies and toddlers because ubiquitous, deadly opioids are "everywhere" and mistaken for candy.<sup>25</sup>

53. In 2016, the President of the United States declared an opioid and heroin epidemic.<sup>26</sup>

<sup>&</sup>lt;sup>22</sup> Id. (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, <u>The Economic Burden of Prescription Opioid Overdose</u>, <u>Abuse</u>, and <u>Dependence in the United States</u>, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.00000000000625).

<sup>&</sup>lt;sup>23</sup> See Rose A. Rudd et al., Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015, 65 Morbidity & Mortality Wkly. Rep. 1445 (2016).

<sup>&</sup>lt;sup>24</sup> See Volkow & McLellan, supra note 2.

<sup>&</sup>lt;sup>25</sup> Julie Turkewitz, <u>'The Pills are Everywhere': How the Opioid Crisis Claims Its Youngest Victims</u>, N.Y. Times, Sept. 20, 2017 ("'It's a cancer,' said [grandmother of dead one-year old], of the nation's opioid problem, 'with tendrils that are going everywhere.'").

<sup>&</sup>lt;sup>26</sup> See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

54. The epidemic of prescription pain medication and heroin deaths is devastating families and communities across the country.<sup>27</sup> Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public, while public entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

55. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional and unlawful conduct, despite their knowledge that such conduct is causing and/or continuing to the national, state and local opioid epidemic.

## 2. North Carolina's Opioid Epidemic.

56. North Carolina has been especially ravaged by the national opioid crisis.

57. North Carolina has an opioid prescription rate of 96.6 per 100 persons, which ranks thirteenth in the country (U.S. median rate: 82.5) and a benzodiazepine prescription rate of 45.3 per 100 persons which ranks fifteenth nationally (U.S. median rate: 37.6).<sup>28</sup>

58. As reported by the North Carolina's Department of Health and Human Services, North Carolina is experiencing an opioid epidemic. From 1999 to 2016, more than 12,000 North Carolinians died from opioid related overdoses.<sup>29</sup> In 2015, there were 1,567 North Carolina overdose deaths, up 14.5 percent from 1,358 North Carolina overdose deaths in 2014.<sup>30</sup> 1,110, or

<sup>&</sup>lt;sup>27</sup> See Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

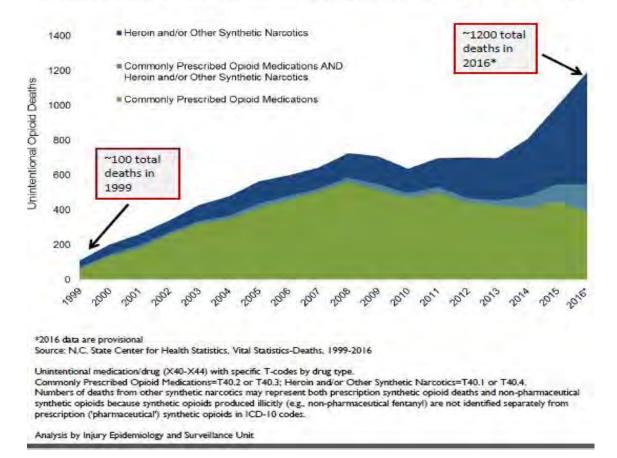
<sup>&</sup>lt;sup>28</sup> See Leonard J. Paulozzi, M.D., *et al.*, *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014). The combination of hydrocodone, oxycodone and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

<sup>&</sup>lt;sup>29</sup> North Carolina Department of Health and Human Resources, Opioid Overdose Fact Sheet, https://files.nc.gov/ncdhhs/Opioid\_Overdose\_Factsheet\_FINAL\_06\_27\_17.pdf.

<sup>&</sup>lt;sup>30</sup> See Drug Overdose Death Data at https://www.cdc.gov/drugoverdose/data/statedeaths.html .

82%, of these overdoses involved opioids.<sup>31</sup> The problem is only getting worse: between 2015 and 2016, opioid related overdose deaths in North Carolina are expected to rise to approximately 1.200.<sup>32</sup>

# Unintentional opioid deaths have increased more than 10 fold\* Heroin or other synthetic narcotics are now involved in over 50% of deaths\*



<sup>&</sup>lt;sup>31</sup> See County-by-County Figures: The Opioid Crisis in North Carolina, at https://governor.nc.gov/news/county-county-figures-opioid-crisis-north-carolina, (last visited October 9, 2017).

<sup>&</sup>lt;sup>32</sup> See North Carolina's Opioid Action Plan 2017-2021, at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%206-23-2017.pdf

59. In 2014, North Carolina experienced 913 deaths, 2,698 hospitalizations and 3,515 emergency department visits related to opioids.<sup>33</sup> During that same year, approximately 349,000 North Carolina residents reported misusing prescription pain relievers, and 7,717,711 prescriptions for opioids were dispensed in North Carolina.<sup>34</sup> Unintentional fatal drug overdoses cost North Carolinians \$1.3 billion in 2015. North Carolina's Department of Health and Human Services estimates opioid related drug deaths cost \$2.1 billion in 2016.<sup>35</sup> From 2011 to 2015, opioid overdose emergency department admissions increased 27%, and the administration of naloxone by EMS personnel increased 34%.<sup>36</sup> It was estimated that emergency department admissions and Naxalone administration will increase by an additional 8.5% and 14.6% respectively for 2016.<sup>37</sup> These rates are expected to continue to rise in 2017.<sup>38</sup>

60. Adults are not the only victims of the opioid epidemic. The opioid epidemic is largely responsible for a 35.6% increase in the number of North Carolina children in foster care from state fiscal years 09/10 through 15/16.<sup>39</sup> From 2004 through 2015, the number of hospitalizations associated with drug withdrawal in newborns increased by a staggering 902%.<sup>40</sup>

61. Data maintained by the Agency for Healthcare Research and Quality for 2007 through 2016 document a sharp increase in opioid-related inpatient hospital stays in North

<sup>34</sup> Id.

<sup>36</sup> Id.

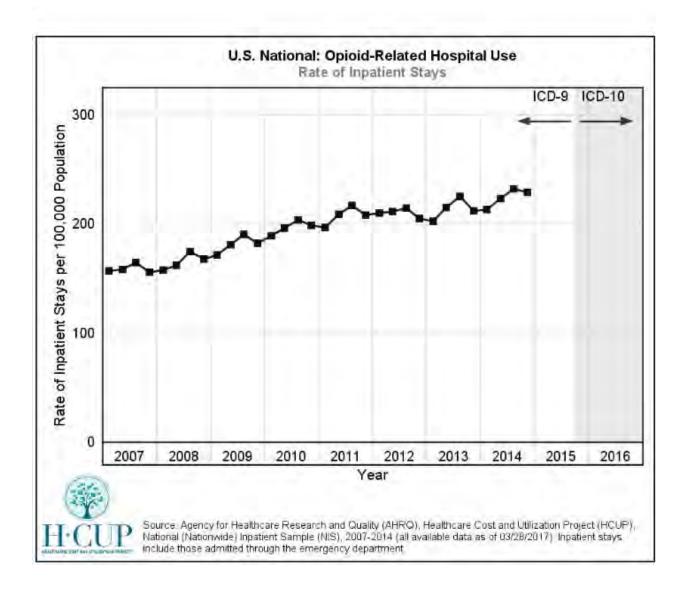
<sup>37</sup> Id.

<sup>38</sup> Id.

<sup>&</sup>lt;sup>33</sup> Id.

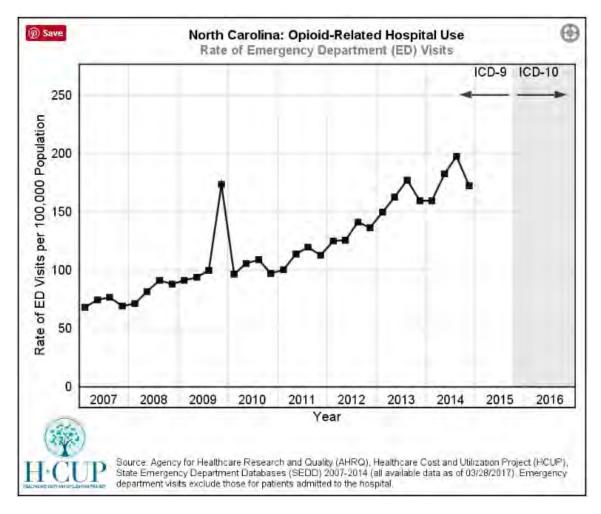
<sup>&</sup>lt;sup>35</sup> See Seeking Community-Level Solutions to Opioid Epidemic, available at http://www.reflector.com/News/2017/09/26/Seeking-community-based-solutions-to-opioid-epidemic.html

 <sup>&</sup>lt;sup>39</sup> See North Carolina's Opioid Action Plan 2017-2021, at https://files.nc.gov/ncdhhs/NC%20Opioid%20Action%20Plan%206-23-2017.pdf, (last visited October 9, 2017).
 <sup>40</sup> Id.



Carolina. The annual rate of such stays per 100,000 population has risen substantially:

62. The rate of opioid-related Emergency Department visits increased 55% in North Carolina between 2009 and 2014:<sup>41</sup>



# 3. Plaintiff Dare County's Opioid Epidemic.

- 63. The opioid epidemic is particularly devastating in Plaintiff's Community.
- 64. From 1999 through 2016, Dare County experienced 76 opiate-related deaths.<sup>42</sup>

<sup>&</sup>lt;sup>41</sup> See Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, *Statistical Brief #219*, *Opioid-Related Inpatient Stays and Emergency Department Visits by State*, 2009-2014, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf, (last visited 10/25/2017).

<sup>&</sup>lt;sup>42</sup> See All Intents Opiate Poisoning Deaths by County: N.C. residents, 1999-2016, available at http://www.injuryfreenc.ncdhhs.gov/DataSurveillance/poisoning/DTH-3-AllOpiatePoisoningsbyCounty-1999-2016.pdf, (last visited 12/6/2017).

65. The Centers for Disease Control estimated that in Dare County approximately 107.6 opioid prescriptions were dispensed per 100 people in 2016. This was well above the national average for 2016 (66.5). In the years leading up to 2016, Dare County's opioid prescription rate remained particularly high with 118.3 prescriptions dispensed per 100 people in 2015, 132.3 in 2014, and 138.7 in 2013, compared to national averages of 70.6 prescriptions per 100 people in 2015, 75.6 in 2014, and 78.1 in 2013.<sup>43</sup>

# **B.** THE MANUFACTURER DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF OPIOIDS.

66. The opioid epidemic did not happen by accident.

67. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

68. Each Manufacturer Defendant has conducted, and has continued to conduct, a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Manufacturer Defendant spent, and continues to spend,

<sup>&</sup>lt;sup>43</sup> U.S. County Prescribing Rate Maps, available at https://www.cdc.gov/drugoverdose/maps/rxcounty2015.html, (last visited 12/6/2017).

millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain.

69. The Manufacturer Defendants have made false and misleading claims, contrary to the language on their drugs' labels, regarding the risks of using their drugs that: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Manufacturer Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.

70. The Manufacturer Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

71. The Manufacturer Defendants' efforts have been wildly successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue annually since 2009.<sup>44</sup> In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."<sup>45</sup> This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

72. The Manufacturer Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

## 1. Each Manufacturer Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids.

73. The Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the State, including in Plaintiff's Community. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State and Plaintiff's Community.

<sup>&</sup>lt;sup>44</sup> See Katherine Eban, Oxycontin: Purdue Pharma's Painful Medicine, Fortune, Nov. 9, 2011, http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, Drugmakers Hooked on \$10bn Opioid Habit, Fin. Times, Aug. 10, 2016, https://www.ft.com/content/f6e989a8-5dac-11e6-bb77a121aa8abd95.

<sup>&</sup>lt;sup>45</sup> Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

74. The Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in and around the State, including in Plaintiff's Community, as they did nationwide. Across the pharmaceutical industry, corporate headquarters fund and oversee "core message" development on a national basis. This comprehensive approach ensures that the Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

75. The Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

### i. Direct Marketing.

76. The Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Manufacturer Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, the Manufacturer Defendants spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

77. Many of the Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with

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physically demanding jobs like construction worker, chef and teacher, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

78. Second, each Manufacturer Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, the Manufacturer Defendants spent in excess of \$168 million on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

79. The Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor and monitor the impact of their core messages. Thus, the Manufacturer Defendants know their detailing to doctors is effective.

80. The Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly

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suggest[] that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."<sup>46</sup>

### ii. Indirect Marketing.

81. The Manufacturer Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "Key Opinion Leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

82. The Manufacturer Defendants deceptively marketed opioids in the State and Plaintiff's Community through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing and distributing this unbranded advertising, the Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, the Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third parties.

<sup>&</sup>lt;sup>46</sup> Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Comme'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010),

http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

83. The Manufacturer Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Manufacturer Defendants used third parties that they funded, directed and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

84. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

85. Borrowing a page from Big Tobacco's playbook, the Manufacturer Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLs and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Manufacturer Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Manufacturer Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and that the compassionate treatment of pain required opioids.

86. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack a reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

87. Pro-opioid doctors are one of the most important avenues that the Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of longterm opioid use. The Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

88. Defendants utilized many KOLs, including many of the same ones.

89. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen

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and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Manufacturer Defendants.

90. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."<sup>47</sup>

91. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids

<sup>&</sup>lt;sup>47</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

does not exist."<sup>48</sup> Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."<sup>49</sup>

92. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants (including nearly \$2 million from Cephalon).

93. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

94. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into

<sup>&</sup>lt;sup>48</sup> Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

<sup>&</sup>lt;sup>49</sup> *Id*.

their own guidelines, indicating, also, their reliance on the Manufacturer Defendants and those under their influence and control.

95. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State and doctors treating members of Plaintiff's Community.<sup>50</sup>

96. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book *Avoiding Opioid Abuse While Managing Pain*—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."<sup>51</sup> Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."<sup>52</sup>

97. The Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Manufacturer Defendants, these

<sup>50</sup> See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

<sup>51</sup> Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).

<sup>&</sup>lt;sup>52</sup> John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html.

"Front Groups" generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Manufacturer Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Manufacturer Defendants.

98. These Front Groups depended on the Manufacturer Defendants for funding and, in some cases, for survival. The Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Manufacturer Defendants made sure that the Front Groups would generate only the messages that the Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

99. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and the Pain & Policy Studies Group ("PPSG").<sup>53</sup>

100. The most prominent of the Manufacturer Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012,

<sup>&</sup>lt;sup>53</sup> See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015),

https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re %20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

primarily from Endo and Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the State and Plaintiff's Community.

101. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of a total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo and others to avoid using its line of credit.

102. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

103. Plaintiff is informed, and believes, that on several occasions, representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

104. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."<sup>54</sup>

105. Another front group for the Manufacturer Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

106. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational

<sup>&</sup>lt;sup>54</sup> Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU\_story.html.

programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

107. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

108. The Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

109. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.<sup>55</sup>

<sup>&</sup>lt;sup>55</sup> The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).

110. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.<sup>56</sup> Treatment guidelines have been relied upon by doctors, especially the general practitioners and family doctors targeted by the Manufacturer Defendants. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

111. At least fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.<sup>57</sup> One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the State and/or Plaintiff's Community during the relevant time period, are still available online, and

<sup>&</sup>lt;sup>56</sup> Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).

<sup>&</sup>lt;sup>57</sup> Id.

were reprinted in the Journal of Pain. The Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Manufacturer Defendants financial support to members of the panel.

112. The Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Manufacturer Defendants determined would reduce prescribing.

## C. THE MANUFACTURER DEFENDANTS' MARKETING SCHEME MISREPRESENTED THE RISKS AND BENEFITS OF OPIOIDS.

## 1. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

113. To falsely assure physicians and patients that opioids are safe, the Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the

drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

114. Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Manufacturer Defendant continued to misrepresent the risks and benefits of longterm opioid use in the State and Plaintiff's Community and each continues to fail to correct its past misrepresentations.

115. Some illustrative examples of the Manufacturer Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

- a. Actavis's predecessor caused a patient education brochure, Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.<sup>58</sup>
- c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly

<sup>&</sup>lt;sup>58</sup> Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."
- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."
- g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."<sup>59</sup>
- h. Consistent with the Manufacturer Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in the State and Plaintiff's Community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.
- i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.<sup>60</sup>
- 116. These claims are contrary to longstanding scientific evidence. A 2016 opioid-

prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is

<sup>&</sup>lt;sup>59</sup> Am. Pain Found., A Policymaker's Guide to Understanding Pain & Its Management (2011) [hereinafter APF, Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

<sup>&</sup>lt;sup>60</sup> Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

"[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."<sup>61</sup> The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."<sup>62</sup>

117. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.<sup>63</sup>

118. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids,

<sup>&</sup>lt;sup>61</sup> Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

<sup>&</sup>lt;sup>62</sup> *Id.* at 2, 25.

<sup>&</sup>lt;sup>63</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer Kaplan A. Davidson, Kleinfeld, and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."<sup>64</sup> Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this State.

119. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Manufacturer Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Manufacturer Defendants misrepresented, to doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. pseudoaddiction) – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

120. To this end, one of Purdue's employees, Dr. David Haddox, invented a phenomenon called "pseudoaddiction." KOL Dr. Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.<sup>65</sup> The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.<sup>66</sup>

<sup>&</sup>lt;sup>64</sup> Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo\_AOD\_030116-Fully\_Executed.pdf.

<sup>&</sup>lt;sup>65</sup> See Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2007) at 62.

<sup>&</sup>lt;sup>66</sup> See Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2d ed. 2012).

- b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which, upon information and belief, promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Upon information and belief, Purdue sponsored a CME program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse". In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

121. In the 2016 CDC Guideline, the CDC implicitly rejected the validity of the pseudoaddiction fallacy.<sup>67</sup>

122. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the Manufacturer Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Manufacturer

<sup>&</sup>lt;sup>67</sup> Supra note 61.

Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

- a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients and not opioids are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.
- 123. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline

explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."<sup>68</sup>

124. A fourth category of deceptive messaging regarding dangerous opioids is the Manufacturer Defendants' false assurances regarding the alleged ease of eliminating opioid dependence. The Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. In truth, the 2016 CDC Guideline explains that the symptoms of opioid withdrawal include abdominal pain, vomiting, diarrhea,

<sup>&</sup>lt;sup>68</sup> *Id.* at 11.

sweating, tremor, tachycardia, drug cravings, anxiety, insomnia, spontaneous abortion and premature labor in pregnant women.<sup>69</sup>

125. The Manufacturer Defendants nonetheless downplayed the severity of opioid detoxification. For example, upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.<sup>70</sup>

126. A fifth category of false, deceptive, and unfair statements the Manufacturer Defendants made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. The Manufacturer Defendants' deceptive claims include:

a. Upon information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have

<sup>&</sup>lt;sup>69</sup> *Id.* at 26.

<sup>&</sup>lt;sup>70</sup> APF, *Policymaker's Guide*, *supra* note 59, at 32.

"no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.<sup>71</sup> This publication is still available online.

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased.... You won't 'run out' of pain relief."<sup>72</sup>

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Upon information and belief, Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.<sup>73</sup>

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.<sup>74</sup>

<sup>&</sup>lt;sup>71</sup> APF, *Treatment Options*, *supra* note 58, at 12.

<sup>&</sup>lt;sup>72</sup> Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

<sup>&</sup>lt;sup>73</sup> APF, *Policymaker's Guide, supra* note 59, at 32.

<sup>&</sup>lt;sup>74</sup> The College on Problems of Drug Dependence, *About the College*, http://cpdd.org (last visited Aug. 21, 2017).

j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Manufacturer Defendants' Front Groups APF and NFP argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.<sup>75</sup>

127. Once again, the 2016 CDC Guideline reveals that the Manufacturer Defendants' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."<sup>76</sup> More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."<sup>77</sup> The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."<sup>78</sup> That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.<sup>79</sup>

128. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can cure addiction and abuse.

129. The Manufacturer Defendants made misleading claims about the ability of their socalled abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised,

<sup>79</sup> Id. at 16.

<sup>&</sup>lt;sup>75</sup> Brief of APF, *supra* note 60, at 9.

<sup>&</sup>lt;sup>76</sup> 2016 CDC Guideline, *supra* note 61, at 22–23.

<sup>&</sup>lt;sup>77</sup> *Id.* at 23–24.

<sup>&</sup>lt;sup>78</sup> *Id.* at 21.

causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.<sup>380</sup> Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection.<sup>381</sup> The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.<sup>382</sup> Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

### 2. The Manufacturer Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

130. To convince doctors and patients that opioids should be used to treat chronic pain, the Manufacturer Defendants also had to persuade them that there was a significant upside to longterm opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq 6$  weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.<sup>83</sup> The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

### 131. Some illustrative examples of the Manufacturer Defendants' false claims are:

<sup>&</sup>lt;sup>80</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

<sup>&</sup>lt;sup>81</sup> *Id*. at 6.

<sup>&</sup>lt;sup>82</sup> *Id.* at 6 n.21.

<sup>&</sup>lt;sup>83</sup> Id. at 15.

- a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.
- b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."
- e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- f. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.
- h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.
- i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient."<sup>84</sup> Upon information and belief, a CME disseminated via

<sup>&</sup>lt;sup>84</sup> See e.g., NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173\_Providence\_RI\_%20Invite.pdf.

webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

- j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."
- k. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain."<sup>85</sup> The Policymaker's Guide was originally published in 2011.
- 1. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

132. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

133. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."<sup>86</sup> And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

<sup>&</sup>lt;sup>85</sup> APF, *Policymaker's Guide*, *supra* note 59, at 29.

<sup>&</sup>lt;sup>86</sup> Letter from Thomas Abrams to Doug Boothe, *supra* note 46.

The Manufacturer Defendants also falsely and misleadingly emphasized or 134. exaggerated the risks of competing medications like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.<sup>87</sup> Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours - a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

<sup>&</sup>lt;sup>87</sup> 2016 CDC Guideline, *supra* note 61, at 12.

135. Purdue's competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Upon information and belief, Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours.

136. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.<sup>88</sup>

137. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be

<sup>&</sup>lt;sup>88</sup> Reply Brief of Amicus Curiae of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at \*4 (footnote omitted).

used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.<sup>89</sup> Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication."<sup>90</sup>

138. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating noncancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

 <sup>&</sup>lt;sup>89</sup> See U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.
 <sup>90</sup> Id.

139. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

Purdue also unlawfully and unfairly failed to report or address illicit and unlawful 140. prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin - the same OxyContin that Purdue had promoted as less addictive - in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action - even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.<sup>91</sup>

141. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse,

<sup>&</sup>lt;sup>91</sup> Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

## **3.** The Manufacturer Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

142. As a part of their deceptive marketing scheme, the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this State and Plaintiff's Community. For example, the Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer Defendants' misrepresentations.

143. The Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.<sup>92</sup> The 2016 CDC Guideline concludes that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who

<sup>&</sup>lt;sup>92</sup> 2016 CDC Guideline, *supra* note 61, at 13.

are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

# 4. The Manufacturer Defendants made Materially Deceptive Statements and Concealed Materials Facts.

144. As alleged herein, the Manufacturer Defendants made and/or disseminated deceptive statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

145. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- d. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- g. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- 1. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- n. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- o. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- p. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;
- q. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing; and
- r. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

146. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Providing needed financial support to pro-opioid pain organizations including over \$5 million to the organization responsible for many of the most egregious misrepresentations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- 1. Directly distributing and assisting in the dissemination of literature written by proopioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- m. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- n. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing.
- 147. Defendant Janssen made and/or disseminated deceptive statements, and concealed

material facts in such a way to make their statements deceptive, including, but not limited to, the

following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;
- i. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;
- j. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- k. Directly distributing and assisting in the dissemination of literature written by proopioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- 1. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;
- m. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and
- n. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing.
- 148. Defendant Cephalon made and/or disseminated untrue, false and deceptive

statements, and concealed material facts in such a way to make their statements deceptive,

including, but not limited to, the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing and speakers' bureau events.
- 149. Defendant Actavis made and/or disseminated deceptive statements, and concealed

material facts in such a way to make their statements deceptive, including, but not limited to, the

### following:

- a. Making deceptive statements concerning the use of opioids to treat chronic noncancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

# 5. The Manufacturer Defendants Fraudulently Concealed Their Misconduct.

150. The Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

151. At all times relevant to this Complaint, the Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own role.

152. Finally, the Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiff or Plaintiff's Community. Thus, the Manufacturer Defendants successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. Plaintiff did not know of the existence or scope of the Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

### D. THE DISTRIBUTOR DEFENDANTS' UNLAWFUL DISTRIBUTION OF OPIOIDS.

153. The Distributor Defendants owe a duty under both federal law (21 U.S.C. § 823, 21 CFR 1301.74), and North Carolina law (*e.g.*, N.C. Gen. Stat. §§ 90-102(e), 90-104, 106-145.10), to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

154. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

155. Each Distributor Defendant repeatedly and purposefully breached its duties under state and federal law. Such breaches are direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's Community.

156. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and in Plaintiff's Community. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

157. The opioid epidemic in North Carolina, including *inter alia* in Plaintiff's Community, remains an immediate *hazard to public health and safety*.

158. The opioid epidemic in Plaintiff's Community is a temporary and continuous *public nuisance* and remains unabated.

159. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

### 1. The Distributor Defendants Have a Duty under Federal and State Law to Guard Against, and Report, Unlawful Diversion and to Report and Prevent Suspicious Orders.

160. Opioids are a controlled substance and, as "Schedule II" drugs, are categorized as dangerous drugs with a "high potential for abuse" which may lead to "severe psychic or physical dependence" under federal and North Carolina law. *See* 21 U.S.C. §§ 812(b)(2)(A) and (C) and N.C. Gen. Stat. § 90-90(1)(a).

As wholesale drug distributors, each Distributor Defendant was required under 161. North Carolina law to register with the North Carolina Department of Health and Human Services and obtain a license as a wholesaler of controlled substances from the North Carolina Commissioner of Agriculture N.C. Gen. Stat. § 90-102-(a)(2); 90-101(a); 106-145.3. Each Distributor Defendant is licensed by the North Carolina Commissioner of Agriculture and is a "registrant" with the North Carolina Department of Health and Human Services as a wholesale distributor in the chain of distribution of Schedule II controlled substances and assumed a duty to comply with all requirements imposed under the regulations adopted by these agencies, all state law, and all requirements imposed under federal law. See N.C. Gen. Stat. § 106-145.10 ("A wholesale drug distributor . . . shall comply with applicable federal, State, and local laws and regulations."); 10A NCAC 26E.0129(a) ("Any person who manufactures, distributes, dispenses, or conducts research with any controlled substance shall comply with Part 1301 of Title 21 of the Code of Federal Regulations . . . . "); N.C. Gen. Stat. § 90-104 ("Each registrant or practitioner manufacturing, distributing, or dispensing controlled substances under this Article shall keep records and maintain inventories in conformance with the record-keeping and the inventory requirements of the federal law . . ."); N.C. Gen. Stat. § 90-102 (a)(2) (a factor considered for registration to manufacture or distribute controlled substances in North Carolina is "[c]ompliance with applicable federal, State and local law").

162. Each Distributor Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. *See* 21 U.S.C. § 823(b), (e); 28 C.F.R. § 0.100. Each Distributor Defendant is a "registrant" as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Those requirements are adopted and incorporated into North Carolina law, as set forth above.

163. Each Distributor Defendant has an affirmative duty under federal and North Carolina law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). North Carolina incorporates these requirements, as set out above, and separately sets out these requirements. *See* N.C. Gen. Stat. § 90-102 (a)(1) (mandating "maintenance of effective controls against diversion of any controlled substances"); N.C. Gen. Stat. § 106-145.7 (for wholesale distributors, mandating use of a security system to provide "protection against ... diversion that is facilitated or hidden by tampering with computers or electronic records").

164. Federal regulations, incorporated by North Carolina law (*see* N.C. Gen. Stat. § 90-104; N.C. GEN. STAT. § 106-145.10; 10A NCAC 26E.0129(a); and N.C. Gen. Stat. § 90-102 (a)(2), similarly impose a non-delegable duty upon wholesale drug distributors to "design and operate a system to disclose to the registrant 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).

165. "Suspicious orders" include orders of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR 1301.74(b); 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 wholesale distributor 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, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor'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 entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

166. North Carolina law makes it "unlawful . . . [t]o furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this Article, or any record required to be kept by this Article," including suspicious order reports, since North Carolina law requires compliance with federal law on this issue. *See* N.C. Gen. Stat. § 90-108.

167. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement* 

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Administration, No. 15-11355 (D.C. Cir. June 30, 2017). Regardless, all flagged orders must be reported. *Id.* 

168. These prescription drugs are regulated for the purpose of providing a "closed" system **intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market**, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.<sup>93</sup>

169. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations define each participant's role and responsibilities.<sup>94</sup>

170. As the DEA advised the Distributor Defendants in a letter to them dated September 27, 2006, wholesale distributors are "one of the key components of the distribution chain. If the closed system is to function properly … 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 … the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."<sup>95</sup>

<sup>93</sup> See 1970 U.S.C.C.A.N. 4566, 4571-72.

<sup>&</sup>lt;sup>94</sup> Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335) (D.C. Cir. Apr. 4, 2016), 2016 WL 1321983, at \*22 [hereinafter Brief for HDMA and NACDS]. The Healthcare Distribution Management Association (HDMA or HMA)—now known as the Healthcare Distribution Alliance (HDA)—is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among others: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation. *See generally* HDA, *About*, https://www.healthcaredistribution.org/about (last visited Aug. 21, 2017). The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents with pharmacies whose membership includes, among others: Walgreen Company, CVS Health, Rite Aid Corporation and Walmart. *See generally* NACDS, *Mission*, https://www.nacds.org/ about/mission/ (last visited Aug. 21, 2017).

<sup>&</sup>lt;sup>95</sup> See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors

171. The Distributor Defendants have admitted that they are responsible for reporting suspicious orders.<sup>96</sup>

172. The DEA sent a letter to each of the Distributor Defendants on September 27, 2006, warning that it would use its authority to revoke and suspend registrations when appropriate. The letter expressly states that a distributor, *in addition* to reporting suspicious orders, 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."<sup>97</sup> The letter also instructs that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."<sup>98</sup> The DEA warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."<sup>99</sup>

173. The DEA sent a second letter to each of the Distributor Defendants on December 27, 2007.<sup>100</sup> This letter reminds the Defendants of their statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."<sup>101</sup> The letter further explains:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders <u>when discovered</u> by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report

<sup>98</sup> *Id.* at 1.

<sup>99</sup> *Id.* at 2.

<sup>101</sup> *Id*.

in view of the prescription drug abuse problem our nation currently faces."), *filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

<sup>&</sup>lt;sup>96</sup> See Brief for HDMA and NACDS, *supra* note 94, 2016 WL 1321983, at \*4 ("[R]egulations . . . in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).").

<sup>&</sup>lt;sup>97</sup> Rannazzisi Letter, *supra* note 95, at 2.

<sup>&</sup>lt;sup>100</sup> See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8.

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 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 segment of the regulated industry.

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 communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by 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.<sup>102</sup>

Finally, the DEA letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."<sup>103</sup>

174. The Distributor Defendants admit that they "have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."<sup>104</sup>

175. The Distributor Defendants knew they were required to monitor, detect, and halt suspicious orders. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers." The guidelines set forth recommended steps in the "due diligence" process, and note in particular: 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.<sup>105</sup>

 $<sup>^{102}</sup>$  *Id*.

<sup>&</sup>lt;sup>103</sup> *Id*.

<sup>&</sup>lt;sup>104</sup> See Brief of HDMA, supra note 19, 2012 WL 1637016, at \*2.

<sup>&</sup>lt;sup>105</sup> Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B).

176. Each of the Distributor Defendants sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Plaintiff's Community and/or to retailers from which Defendants knew prescription opioids were likely to be diverted to Plaintiff's Community.

177. Each Distributor Defendant owes a duty to monitor and detect suspicious orders of prescription opioids.

178. Each Distributor Defendant owes a duty under federal and state law to investigate and refuse suspicious orders of prescription opioids.

179. Each Distributor Defendant owes a duty under federal and state law to report suspicious orders of prescription opioids.

180. Each Distributor Defendant owes a duty under federal and state law to prevent the diversion of prescription opioids into illicit markets in the State and Plaintiff's Community.

181. The foreseeable harm resulting from a breach of these duties is the diversion of prescription opioids for nonmedical purposes and subsequent plague of opioid addiction.

182. The foreseeable harm resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Plaintiff's Community and the damages caused thereby.

#### 2. The Distributor Defendants Breached their Duties.

183. Because distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective

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controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system collapses.<sup>106</sup>

184. The sheer volume of prescription opioids distributed to pharmacies in the Plaintiff's Community, and/or to pharmacies from which the Distributor Defendants knew the opioids were likely to be diverted into Plaintiff's Community, is excessive for the medical need of the community and facially suspicious. Some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.<sup>107</sup>

185. The Distributor Defendants failed to report "suspicious orders" originating from Plaintiff's Community, or which the Distributor Defendants knew were likely to be diverted to Plaintiff's Community, to the federal and state authorities, including the DEA and/or the NCDHHS.

186. The Distributor Defendants unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

187. The Distributor Defendants breached their duty to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates originating from Plaintiff's Community, and/or in areas from which the Distributor Defendants knew opioids were likely to be diverted to Plaintiff's Community.

<sup>&</sup>lt;sup>106</sup> See Rannazzisi Decl. ¶ 10, filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-2.

<sup>&</sup>lt;sup>107</sup> Masters Pharmaceuticals, Inc., 80 Fed. Reg. 55,418-01, 55,482 (Sept. 15, 2015) (citing Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,316, 62,322 (2012)).

188. The Distributor Defendants breached their duty to maintain effective controls against diversion of prescription opiates into other than legitimate medical, scientific, and industrial channels.

189. The Distributor Defendants breached their duty to "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and failed to inform the authorities including the DEA of suspicious orders when discovered, in violation of their duties under federal and state law.

190. The Distributor Defendants breached their duty to exercise due diligence to avoid filling suspicious orders that might be diverted into channels other than legitimate medical, scientific and industrial channels.<sup>108</sup>

191. The federal and state laws at issue here are public safety laws.

192. The Distributor Defendants' violations of public safety statutes constitute prima facie evidence of negligence under state law.

193. The unlawful conduct by the Distributor Defendants is purposeful and intentional. The Distributor Defendants refuse to abide by the duties imposed by federal and state law which are required to legally acquire and maintain a license to distribute prescription opiates.

194. The Distributor Defendants acted with actual malice in breaching their duties, *i.e.*, they have acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

195. The Distributor Defendants' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant authorities demonstrates wanton, willful, or reckless conduct or criminal

<sup>&</sup>lt;sup>108</sup> See Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 206 (D.D.C. 2012).

indifference to civil obligations affecting the rights of others and justifies an award of punitive damages.

# **3.** The Distributor Defendants Have Sought to Avoid and Have Misrepresented their Compliance with their Legal Duties.

196. The Distributor Defendants have repeatedly misrepresented their compliance with their legal duties under state and federal law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

197. Distributor Defendants have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run the Distributor Defendants, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- a. The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to investigate orders (e.g., by interrogating pharmacies and physicians) and take action to halt suspicious orders before they are filled."<sup>109</sup>
- b. The Associations argued that, "DEA now appears to have changed its position to require that distributors not only report suspicious orders, but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."<sup>110</sup>

<sup>&</sup>lt;sup>109</sup> Brief for HDMA and NACDS, *supra* note 94, 2016 WL 1321983, at \*4-5.

<sup>&</sup>lt;sup>110</sup> *Id.* at \*8 (citations and quotation marks omitted).

- c. The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."<sup>111</sup>
- d. The Associations complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."<sup>112</sup>
- e. The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."<sup>113</sup>
- f. Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."<sup>114</sup>
- 198. The positions taken by the trade groups are emblematic of the position taken by the

Distributor Defendants in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.<sup>115</sup>

199. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting. *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order." *Id.* at 212. Master Pharmaceutical was in violation

<sup>&</sup>lt;sup>111</sup> *Id.* at \*14.

<sup>&</sup>lt;sup>112</sup> *Id.* at \*22.

<sup>&</sup>lt;sup>113</sup> *Id.* at \*24–25.

<sup>&</sup>lt;sup>114</sup> *Id.* at 26.

<sup>&</sup>lt;sup>115</sup> See Brief of HDMA, supra note 19, 2012 WL 1637016, at \*3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").

of legal requirements because it failed to conduct necessary investigations and filled suspicious orders. *Id.* at 218–19, 226. A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id.* at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id.* at 220.

200. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] 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."<sup>116</sup> Further, the 2017 Agreement specifically finds that McKesson "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)."117 McKesson admitted that, during this time period, it "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

<sup>&</sup>lt;sup>116</sup> See Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.

<sup>&</sup>lt;sup>117</sup> *Id.* at 4.

*et seq.*, at the McKesson Distribution Centers." Due to these violations, McKesson agreed that its authority to distribute controlled substances from some of its distribution centers would be partially suspended.<sup>118</sup>

201. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.<sup>119</sup> In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.<sup>120</sup> The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."<sup>121</sup> As a result of these violations, McKesson was fined and required to pay to the United States \$150,000,000.<sup>122</sup>

202. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

203. Because of the Distributor Defendants' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example,

<sup>&</sup>lt;sup>118</sup> *Id.* at 6.

<sup>&</sup>lt;sup>119</sup> *Id.* at 4.

<sup>&</sup>lt;sup>120</sup> Id.

<sup>&</sup>lt;sup>121</sup> *Id.*; *see also* Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], 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."), https://www.justice.gov/opa/press-release/file/928471/download.

<sup>&</sup>lt;sup>122</sup> See 2017 Settlement Agreement and Release, supra note 121, at 6.

in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.<sup>123</sup> The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.<sup>124</sup>

These actions include the following:

- g. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;
- h. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- i. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;
- j. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;
- k. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;
- 1. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required

<sup>&</sup>lt;sup>123</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

<sup>&</sup>lt;sup>124</sup> *Id.* 

by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

- m. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");
- n. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;
- o. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- p. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

204. Rather than abide by their non-delegable duties under public safety laws, the Distributor Defendants, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license

from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.<sup>125</sup>

205. In addition to taking actions to limit regulatory prosecutions and suspensions, the Distributor Defendants undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Distributor Defendants attempted to assure the public they were working to curb the opioid epidemic.

206. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."<sup>126</sup> Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

207. Similarly, Defendant McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."<sup>127</sup> Again, given

<sup>125</sup> See Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-

d7c704ef9fd9 story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf story.html; Eric Eyre, DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

<sup>&</sup>lt;sup>126</sup> Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0\_story.html.

<sup>&</sup>lt;sup>127</sup> Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e\_story.html.

McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

208. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Distributor Defendants successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiff now asserts. The Plaintiff did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

209. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, and in Plaintiff's Community.

210. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Distributor Defendants, pay fines as a cost of doing business in an industry that generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

211. The wrongful actions and omissions of the Distributor Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis, and many of the actions are alleged in greater detail in Plaintiff's racketeering allegations below.

212. The Distributor Defendants have abandoned their duties imposed under federal and state law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the State and Plaintiff's Community.

### E. THE MANUFACTURER DEFENDANTS' UNLAWFUL FAILURE TO PREVENT DIVERSION AND MONITOR, REPORT, AND PREVENT SUSPICIOUS ORDERS.

213. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Manufacturer Defendants under federal law.

214. Under North Carolina and federal law, the Manufacturer Defendants were required to comply with substantially the same licensing and permitting requirements as the Distributor Defendants and the same rules regarding prevention of diversion and reporting suspicious orders, as set out above.

215. Like the Distributor Defendants, the Manufacturer Defendants were required to register with the DEA to manufacture schedule II controlled substances, like prescription opioids.

See 21 U.S.C. § 823(a). A requirement of such registration is the:

maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes ....

21 USCA § 823(a)(1) (emphasis added).

216. Additionally, as "registrants" under Section 823, the Manufacturer Defendants

were also required to monitor, report, and prevent suspicious orders of controlled substances:

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.

21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 ("Any term used in this part shall have the

definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter."); 21

C.F.R. § 1300.01 ("Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958)."

217. As manufacturers of controlled substances, each Manufacturer Defendant was required under North Carolina law to register with the North Carolina Department of Health and Human Services N.C. Gen. Stat. § 90-102(a)(2); 90-101(a). Each Manufacturer Defendant is licensed by the North Carolina Commissioner of Agriculture and is a "registrant" with the North Carolina Department of Health and Human Services as a manufacturer of Schedule II controlled substances and assumed a duty to comply with all requirements imposed under the regulations adopted by these agencies, all state law, and all requirements imposed under federal law. See 10A NCAC 26E.0129(a) ("Any person who manufactures, distributes, dispenses, or conducts research with any controlled substance shall comply with Part 1301 of Title 21 of the Code of Federal Regulations . . . . "); N.C. Gen. Stat. § 90-104 ("Each registrant or practitioner manufacturing, distributing, or dispensing controlled substances under this Article shall keep records and maintain inventories in conformance with the record-keeping and the inventory requirements of the federal law ..."); N.C. Gen. Stat. § 90-102 (a)(2) (a factor considered for registration to manufacture or distribute controlled substances in North Carolina is "[c]ompliance with applicable federal, State and local law").

218. Like the Distributor Defendants, the Manufacture Defendants breached their duties under federal and state law.

219. The Manufacturer Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Manufacturer Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the

manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Manufacturer Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

220. Federal statutes and regulations – and North Carolina law incorporating these requirements – are clear: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion." 21 C.F.R. § 1301.74; 21 U.S.C.A. § 823(a)(1).

221. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.<sup>128</sup>

222. In the press release accompanying the settlement, the Department of Justice stated: Mallinckrodt 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 . . . . Mallinckrodt's actions and omissions formed a link in the chain

<sup>&</sup>lt;sup>128</sup> See Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders

of supply that resulted in millions of oxycodone pills being sold on the street. . . . "Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."<sup>129</sup>

223. Among the allegations resolved by the settlement, the government alleged "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 . . . [and] 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."<sup>130</sup>

224. The Memorandum of Agreement entered into by Mallinckrodt ("2017 Mallinckrodt MOA") avers "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."<sup>131</sup>

225. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

i. conduct adequate due diligence of its customers;

<sup>130</sup> *Id*.

<sup>&</sup>lt;sup>129</sup> Id.

<sup>&</sup>lt;sup>131</sup> Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, PLC. and its subsidiary Mallinckrodt, LLC (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.<sup>132</sup>

226. Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." Mallinckrodt further agreed that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and would "design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify

<sup>&</sup>lt;sup>132</sup> 2017 Mallinckrodt MOA at p. 2-3.

DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."<sup>133</sup>

227. Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."<sup>134</sup>

228. The same duties imposed by federal law on Mallinckrodt were imposed upon all Distributor Defendants.

229. The same business practices utilized by Mallinckrodt regarding "charge backs" and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, the other Manufacturer Defendants.

230. Through, *inter alia*, the charge back data, the Manufacturer Defendants could monitor suspicious orders of opioids.

231. The Manufacturer Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law.

232. The Manufacturer Defendants' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful.

<sup>&</sup>lt;sup>133</sup> *Id.* at 3-4.

<sup>&</sup>lt;sup>134</sup> *Id.* at p.5.

233. The Manufacturer Defendants have misrepresented their compliance with federal and state law.

234. The Manufacturer Defendants enabled the supply of prescription opioids to obviously suspicious physicians and pharmacies, enabled the illegal diversion of opioids, aided criminal activity and disseminated massive quantities of prescription opioids into the black market.

235. The wrongful actions and omissions of the Manufacturer Defendants which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's racketeering allegations below.

236. The Manufacturer Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Plaintiff's Community.

# F. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED THE HARM ALLEGED HEREIN AND SUBSTANTIAL DAMAGES.

237. As the Manufacturer Defendants' efforts to expand the market for opioids increased so have the rates of prescriptions and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the State and the Plaintiff's Community. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into Plaintiff's Community, fueling the epidemic.

238. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."<sup>135</sup>

239. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.<sup>136</sup>

240. The epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."<sup>137</sup>

241. The increased abuse of prescription painkillers along with growing sales has contributed to a large number of overdoses and deaths.<sup>138</sup>

242. As shown above, the opioid epidemic has escalated in Plaintiff's Community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opiates.

243. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiffs' Community and areas from which such opioids are being diverted into Plaintiff's Community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

244. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

<sup>&</sup>lt;sup>135</sup> See Dart et al., supra note 11.

<sup>&</sup>lt;sup>136</sup> See Volkow & McLellan, supra note 2.

<sup>&</sup>lt;sup>137</sup> See Califf et al., supra note 3.

<sup>&</sup>lt;sup>138</sup> See Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., *supra* note 13.

<sup>194</sup> 

245. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety in the State and in Plaintiff's Community.

246. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Plaintiff's Community.

247. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the State and Plaintiff's Community. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff and Plaintiff's Community.

248. Defendants intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein. Plaintiff also seeks the means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct.

249. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs associated with past efforts to eliminate the hazards to public health and safety.

250. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

251. To eliminate the hazard to public health and safety, and abate the public nuisance, a "multifaceted, collaborative public health and law enforcement approach is urgently needed."<sup>139</sup>

<sup>&</sup>lt;sup>139</sup> See Rudd et al., supra note 18, at 1145.

252. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.<sup>140</sup>

253. The actions of the Defendants, jointly and severally, have proximately caused damages including but not limited to the following:

- a. The costs of developing and maintaining various programs, departments, agencies, courts, drug courts, systems, personnel, past, present, and future, that the Plaintiff has been and will be required to undertake at a substantial expense to deal with and allow for the abatement of the opioid crisis and its effects on Dare County and its citizens, and citizens of the surrounding areas and counties who require such services in Dare County while inside Dare County.
- b. The actions of the Defendants have proximately caused an increase in the financial pressures of the County, for the court systems, law enforcement in the county, emergency medical services, family abuse abatement, rescue costs for its citizens for overdoses, mental health department services, health department services, and a substantial increase on all county resources due to the opioid crisis.
- c. The Plaintiff has endured increased costs for foster care, placement, and court hearings, emergency call and response volume, treatment for the uninsured by public health departments, medical examiner costs, increased sheriff's office costs, substance abuse treatment costs, costs of overdose medications, increased jail costs, costs for dealing with babies delivered with positive toxicology or Neonatal

<sup>&</sup>lt;sup>140</sup> See Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH\_OPIOID\_EPIDEMIC\_REPORT.pdf.

Abstinence Syndrome (NAS), court costs, additional training for all county personnel to deal with the opioid crisis, 911 communications costs, additional costs to the Department of Social Services and other such related costs.

d. In order to abate the problem, in the future, not only will the above costs be accrued but additional costs for education in the schools, education for the medical community, additional law-enforcement agencies such as an Opioid Task Force and monitoring of the opioid databases, and additional costs for treatment facilities, half-way houses, and other treatment options, and facilities, including emergency medical services follow-up care programs, or other costs, damages, and treatments found and described in the Report of the Presidents Commission on the Opioid Crisis.

254. The above in no way includes all potential damages, but is a portion of the damages attributable to the opioid crisis, with such additional damages to be determined by further investigation and identification.

255. Such damages were proximately caused by the actions of the Defendants, jointly and severally, causing damages to the Plaintiff and its citizens, and substantial increased financial burdens.

256. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."<sup>141</sup>

<sup>&</sup>lt;sup>141</sup> See Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx\_abuse\_plan.pdf.

257. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's Community.

# G. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTED STATUTES OF LIMITATIONS AS DEFENSES.

### **1. Continuing Wrong Doctrine.**

258. Plaintiff contends it continues to suffer harm from the continual unlawful actions by the Defendants.

259. The continued tortious and unlawful conduct by the Defendants are continuing violations of federal and state law causing a distinct injury instead of continual ill effects from an original violation. The effects of Defendants' violative acts are cumulative. The damages have not occurred all at once but have continued to occur after each violation and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

# 2. Equitable Estoppel.

260. Defendants are equitably estopped from relying upon a statute of limitations defense, to the extent any such defense even applies to Plaintiff's claims, because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the State, the Plaintiff, and Plaintiff's Community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the State and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the

public, including the State, the Plaintiff, and Plaintiff's Community, that they are working to curb the opioid epidemic.

261. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."<sup>142</sup>

262. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."<sup>143</sup>

263. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:<sup>144</sup>

- a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- b. "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."
- d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."
- e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

<sup>&</sup>lt;sup>142</sup> Bernstein et al., *supra* note 126.

<sup>&</sup>lt;sup>143</sup> Higham et al., *supra* note 127.

<sup>&</sup>lt;sup>144</sup> Brief for HDMA and NACDS, *supra* note 94, 2016 WL 1321983, at \*3-4, \*25.

Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

264. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, which will confirm their identities and the extent of their wrongful and illegal activities.

265. The Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Manufacturer Defendants invented "pseudoaddiction" and promoted it to an unsuspecting medical community. Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Manufacturer Defendants recommended to the medical community that dosages be increased, without disclosing the risks. Manufacturer Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the State, and Plaintiff's Community were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the State and in Plaintiff's Community

266. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's Community. Plaintiff and Plaintiff's Community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

267. The Plaintiff and Plaintiff's Community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

## 3. Fraudulent Concealment.

268. The Plaintiff's claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiff and Plaintiff's community. The Plaintiff did not know, or could not have known through the exercise of reasonable diligence, of its cause of action, as a result of Defendants' conduct.

269. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed.

270. In light of their statements to the media, in legal filings, and settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

271. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiff was unable to obtain vital information bearing on its claims absent any fault or lack of diligence on its part.

### V. LEGAL CAUSES OF ACTION

# COUNT I PUBLIC NUISANCE (Against all Defendants)

272. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

273. Defendants' unlawful actions have created a public nuisance under North Carolina law, and Plaintiff brings an action under both common law and statutory authority for abatement of that nuisance. *See* N.C. Gen. Stat. §153A-140 (granting Dare County power to abate public health nuisances within its boundaries); N.C. Gen. Stat. § 19-1 (a) (The erection, establishment, continuance, maintenance, use, ownership or leasing of any building or place for the purpose . . . illegal possession or sale of controlled substances as defined in the North Carolina Controlled Substances Act . . . shall constitute a nuisance.).

274. Plaintiff alleges that Defendants wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public.

275. The Defendants have intentionally and/or unlawfully created an absolute nuisance.

276. Plaintiff and the residents of Plaintiff's Community have a common right to be free from conduct that creates an unreasonable jeopardy to the public health, welfare and safety, and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

277. Defendants intentionally, unlawfully, and recklessly manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to Plaintiff's Community, resulting in addiction and abuse, an elevated level of crime, death and injuries to the

residents of Plaintiff's Community, a higher level of fear, discomfort and inconvenience to the residents of Plaintiff's Community, and direct costs to Plaintiff's Community.

278. Defendants have unlawfully and/or intentionally caused and permitted dangerous drugs under their control to be diverted such as to injure the Plaintiff's Community and its residents.

279. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct was illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

280. Defendants have caused a significant and unreasonable interference with the public health, safety, welfare, peace, comfort and convenience, and ability to be free from disturbance and reasonable apprehension of danger to person or property.

281. Defendants' conduct in illegally distributing and selling prescription opioids, or causing such opioids to be distributed and sold, where Defendants know, or reasonably should know, such opioids will be diverted and possessed and/or used illegally Plaintiff's Community is of a continuing nature.

282. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

283. A violation of any rule or law controlling the distribution of a drug of abuse in Plaintiff's Community and the State is a public nuisance.

284. Defendants' distribution of opioids while failing to maintain effective controls against diversion was proscribed by statute and regulation.

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285. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be illegally distributed and possessed in Plaintiff's Community will be diverted, leading to abuse, addiction, crime, and public health costs.

286. Because of the continued use and addiction caused by these illegally distributed opioids, the public will continue to fear for its health, safety and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

287. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

288. Defendants know, or reasonably should know, that their conduct causes an unreasonable invasion of the public right to health, safety and welfare and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

289. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in Plaintiff's Community. Defendants are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law. *See*, e.g., 21 U.S.C. § 812 (b)(2).

290. Defendants' conduct in marketing, distributing, and selling prescription opioids which the defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medical use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents in Plaintiff's Community and otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

291. It is, or should be, reasonably foreseeable to defendants that their conduct will cause deaths and injuries to residents in Plaintiff's Community, and will otherwise significantly and unreasonably interfere with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

292. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes in Plaintiff's Community not only causes deaths and injuries, but also creates a palpable climate of fear among residents in Plaintiff's Community where opioid diversion, abuse, addiction are prevalent and where diverted opioids tend to be used frequently.

293. Defendants' conduct makes it easier for persons to divert prescription opioids, constituting a dangerous threat to the public.

294. Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Because of Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

295. The presence of diverted prescription opioids in Plaintiff's Community, and the consequence of prescription opioids having been diverted in Plaintiff's Community, proximately results in significant costs to the Plaintiff and to Plaintiff's Community in order to enforce the law, equip its police officers and medical services or first responders, treat the victims of opioid abuse and addiction, and provide other services.

296. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiff's Community a safer place to live.

297. Defendants' conduct is a direct and proximate cause of deaths and injuries to the residents of Plaintiff's Community, costs borne by Plaintiff's Community and the Plaintiff, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property.

298. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety and welfare of the residents of Plaintiff's Community, creating an atmosphere of fear and addiction that tears at the residents' sense of well-being and security. Plaintiff has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

299. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create in Plaintiff's Community, however, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully and/or unlawfully and/or unlawfully and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship and failed to halt suspicious orders of opioids, or caused such orders to be shipped. Defendants intentionally

and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

300. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, that the opioids would be diverted, and create an opioid abuse nuisance in Plaintiff's Community.

301. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm, and did cause substantial harm.

302. The damages available to the Plaintiff include, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance which the government seeks to abate. Defendants' conduct is ongoing and persistent, and the Plaintiff seeks all damages flowing from Defendants' conduct. Plaintiff further seeks to abate the nuisance and harm created by Defendants' conduct.

303. As a direct result of Defendants' conduct, the Plaintiff and Plaintiff's Community have suffered actual injury and damages including, but not limited to, significant expenses for first responders, as well as emergency, health, prosecution, jail, social, and other services. The Plaintiff here seeks recovery for its own harm.

304. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include, inter alia, health services, law enforcement expenditures, and costs related to opioid addiction treatment and overdose prevention.

305. The Plaintiff further seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and interference with a right common to the public.

306. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia abatement, compensatory damages, and punitive damages from the Defendants for the creation of a public nuisance, attorney fees and costs, and pre- and post-judgment interest.

307. Defendants' intentional and unlawful actions and omissions and unreasonable interference with a right common to the public are of a continuing nature.

308. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the Plaintiff's community. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and severe addiction. Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

309. The public nuisance created by Defendants' actions is substantial and unreasonable – it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gate-keeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to, the following:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

- b. Even children have fallen victim to the opioid epidemic. Easy access to prescription opioids made opioids a recreational drug of choice among teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.
- c. Even those residents of Plaintiffs' Community who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gatekeeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.
- d. The opioid epidemic has increased health care costs.
- e. Employers have lost the value of productive and healthy employees.
- f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.
- g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More prescription opioids sold by Defendants led to more addiction, with many addicts turning from prescription opioids to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.
- h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement.
- i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the Plaintiffs' Community.
- j. Defendants' interference with the comfortable enjoyment of life in the Plaintiffs' Community is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions; and
- k. Opioid abuse and addiction has triggered property crimes throughout Plaintiff's Community as addicts search for the means to finance their addiction.

310. The Plaintiff and Plaintiff's Community have sustained specific and special injuries because its damages include *inter alia* health services, social services and first responders' expenditures, as described in this Complaint.

311. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity and fraudulent misrepresentations. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

312. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

#### COUNT II RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961, et seq. (Against All Defendants)

313. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

314. Plaintiff brings this Count on behalf of itself against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

315. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

316. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United State v. Turkette*, 452 U.S. 576, 580 (1981).

317. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity." *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id*.

318. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed-system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they

manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

319. The closed-system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling the quantities of the basic ingredients needed for the manufacture of [controlled substances]."<sup>145</sup>

320. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.<sup>146</sup> As discussed in detail below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.<sup>147</sup> In doing so, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market which allowed them to generate obscene profits.

321. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants, and executed in perfect

<sup>&</sup>lt;sup>145</sup> 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\_0.pdf).

<sup>&</sup>lt;sup>146</sup> 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

<sup>&</sup>lt;sup>147</sup> 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

harmony by each of them. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), whose purpose was to engage in the unlawful sales of opioids, deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct, and pattern of racketeering activity, they were able to extract billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced tens of millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained in detail below, the RICO Defendants' misconduct violated Section 1962(c) and Plaintiff is entitled to treble damages for its injuries under 18 U.S.C. § 1964(c).

322. Alternatively, the RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")<sup>148</sup> is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

<sup>&</sup>lt;sup>148</sup> Health Distribution Alliance, <u>History</u>, Health Distribution Alliance, (last accessed on September 15, 2017), https://www.healthcaredistribution.org/about/hda-history.

323. On information and belief, each of the RICO Defendants is a member, participant, and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

324. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. And, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

325. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

## A. THE OPIOID DIVERSION ENTERPRISE

326. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.<sup>149</sup> The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.<sup>150</sup> Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.<sup>151</sup> As reflected in comments from United

<sup>&</sup>lt;sup>149</sup> Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12cv-185 (Document 14-2 February 10, 2012).

<sup>&</sup>lt;sup>150</sup> See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

<sup>&</sup>lt;sup>151</sup> Gonzalez v. Raich, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."<sup>152</sup> Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."<sup>153</sup> Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.<sup>154</sup> All registrants -- manufacturers and distributors alike -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.<sup>155</sup> When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.<sup>156</sup> The result is the scourge of addiction that has occurred.

327. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and to inform the

<sup>&</sup>lt;sup>152</sup> See H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

<sup>&</sup>lt;sup>153</sup> See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\_0.pdf).

<sup>&</sup>lt;sup>154</sup> See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

<sup>&</sup>lt;sup>155</sup> *Id*.

<sup>&</sup>lt;sup>156</sup> Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12cv-185 (Document 14-2 February 10, 2012).

DEA of any suspicious orders.<sup>157</sup> The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."<sup>158</sup>

328. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."<sup>159</sup> When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class by all manufacturers;
- c. Trends in the national rate of disposal of the basic class;
- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

329. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.<sup>160</sup>

<sup>&</sup>lt;sup>157</sup> Joseph T. Rannazzisi, <u>In Reference to Registration # RC0183080 (September 27, 2006)</u>; Joseph T. Rannazzisi, <u>In Reference to Registration # RC0183080</u> (December 27, 2007).

<sup>&</sup>lt;sup>158</sup> <u>Suggested Questions a Distributor should ask prior to shipping controlled substances</u>, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm\_industry/14th\_pharm/levinl\_ques.pdf).

<sup>&</sup>lt;sup>159</sup> 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\_0.pdf).

<sup>&</sup>lt;sup>160</sup> See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United State Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony\_0.pdf).

330. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.<sup>161</sup>

331. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market, in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

332. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the county with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.<sup>162</sup> On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.<sup>163</sup>

333. The Opioid Diversion Enterprise was and is a shockingly successful endeavor. It Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. But, it

<sup>&</sup>lt;sup>161</sup> Id. (citing 21 U.S.C. 842(b)).

<sup>&</sup>lt;sup>162</sup> Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States. Am J Public Health. 2014;104(2):e52-9.

<sup>&</sup>lt;sup>163</sup> Matthew Perrone, <u>Pro-Painkiller echo chamber shaped policy amid drug epidemic</u>, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public.

334. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and then requesting the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

335. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations<sup>164</sup> The

<sup>&</sup>lt;sup>164</sup> See <u>HDMA is now the Healthcare Distribution Alliance</u>, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\_story.html;

HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the Pain Care Forum and HDA have devoted millions of dollars to lobbying efforts in recent years.

336. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating state and federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

337. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across states lines, such as manufacture, sale, distribution, and shipment of prescription opioids throughout the

Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-forinvestigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

County and this jurisdiction, and the corresponding payment and/or receipt of money from the sale of the same.

338. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

339. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the RICO Defendants participated in, and are members of, the enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

340. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum, the HDA, and through their contractual relationships.

341. The Pain Care Forum ("PCF") has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

342. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drugmakers <u>and their allies</u> shaped the national response to the ongoing wave of prescription opioid abuse."<sup>165</sup> Specifically, PCF members spent over \$740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.<sup>166</sup>

343. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.<sup>167</sup> In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan), and Teva (the parent company of Cephalon).<sup>168</sup> Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.<sup>169</sup> Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

<sup>&</sup>lt;sup>165</sup> Matthew Perrone, <u>Pro-Painkiller echo chamber shaped policy amid drug epidemic</u>, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic (emphasis added).

<sup>&</sup>lt;sup>166</sup> *Id*.

<sup>&</sup>lt;sup>167</sup> <u>PAIN CARE FORUM 2012 Meetings Schedule</u>, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

<sup>&</sup>lt;sup>168</sup> *Id.* Plaintiff is informed and believes that Mallinckrodt became an active member of the PCF sometime after 2012.

<sup>&</sup>lt;sup>169</sup> *Id.* The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. <u>Executive Committee</u>, Healthcare Distribution Alliance (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/executive-committee.

344. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person" at the monthly meetings. And, the meeting schedule indicates that the quarterly and year-end meetings included a "Guest Speaker."

345. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis, either directly or through their trade organization, in a coalition of drugmakers and their allies whose sole purpose was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

346. Second, the HDA -- or Healthcare Distribution Alliance -- led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA.<sup>170</sup> And, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

<sup>&</sup>lt;sup>170</sup> <u>Manufacturer Membership</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/membership/manufacturer.

347. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."<sup>171</sup> Clearly, the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

348. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.<sup>172</sup> The manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year end net sales through any HDA distributors, including but not limited to, Defendants AmerisourceBergen, Cardinal Health, and McKesson.<sup>173</sup>

349. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces and working groups, including:

<sup>&</sup>lt;sup>171</sup> <u>Manufacturer Membership Benefits</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

<sup>&</sup>lt;sup>172</sup> <u>Manufacturer Membership Application</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

<sup>&</sup>lt;sup>173</sup> Id.

- a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."<sup>174</sup>
- b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.<sup>175</sup>
- c. Health, Beauty and Wellness Committee: "This committee conducts research, as well as creates and exchanges industry knowledge to help shape the future of the distribution for health, beauty and wellness/consumer products in the healthcare supply chain." Participation in this committee includes distributors and manufacturer members.<sup>176</sup>
- d. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.<sup>177</sup>
- e. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.<sup>178</sup>
- f. Bar Code Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.<sup>179</sup>
- g. eCommerce Task Force: Participation includes Distributor, Manufacturer and Service Provider Members.<sup>180</sup>

- <sup>178</sup> Id.
- <sup>179</sup> Id.
- $^{180}$  *Id*.

<sup>&</sup>lt;sup>174</sup> <u>Councils and Committees</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/councils-and-committees

<sup>&</sup>lt;sup>175</sup> Id.

<sup>&</sup>lt;sup>176</sup> Id.

<sup>&</sup>lt;sup>177</sup> Id.

# h. ASN Working Group: Participation includes Distributor, Manufacturer and Service Provider Members.<sup>181</sup>

350. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation includes Distributor and Manufacturer Members.<sup>182</sup>

351. The councils, committees, task forces and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization.

352. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA, and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."<sup>183</sup> The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."<sup>184</sup> The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high-level of leadership. And, it

<sup>&</sup>lt;sup>181</sup> *Id*.

<sup>&</sup>lt;sup>182</sup> Id.

<sup>&</sup>lt;sup>183</sup> <u>Business and Leadership Conference – Information for Manufacturers</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), <u>https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers</u>.

<sup>&</sup>lt;sup>184</sup> Id.

is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.<sup>185</sup>

353. Third, the RICO Defendants maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

354. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.<sup>186</sup> As reported in the Washington Post, identified by Senator McCaskill, and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.<sup>187</sup> On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.<sup>188</sup> The Manufacturer Defendants used this information to gather high-level data regarding overall

<sup>&</sup>lt;sup>185</sup> <u>2015 Distribution Management Conference and Expo</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

<sup>&</sup>lt;sup>186</sup> Lenny Bernstein & Scott Higham, The government's struggle to hold opioid manufacturers accountable, The Washington Post. (April 2017), https://www.washingtonpost.com/graphics/investigations/dea-2, mallinckrodt/?utm term=.b24cc81cc356; see also, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioidinvestigation-letter-manufacturers.png; Claire McCaskill, Letters From Sen. 2017), (March 28, https://www.mccaskill.senate.gov/opioid-investigation; Purdue Managed Markets, Purdue Pharma, (accessed on September 14, 2017), http://www.purduepharma.com/payers/managed-markets/.

<sup>&</sup>lt;sup>187</sup> *Id*.

<sup>&</sup>lt;sup>188</sup> <u>Webinars</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

355. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

356. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

357. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum -- whose members include the Manufacturers and the Distributors' trade association has been lobbying on behalf of the Manufacturers and Distributors

for "more than a decade."<sup>189</sup> And, from 2006 to 2016 the Distributors and Manufacturers worked together through the Pain Care Forum to spend over \$740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures.<sup>190</sup> Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.<sup>191</sup>

358. As described above, the RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

#### **B.** CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

359. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits, as follows:

360. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

<sup>&</sup>lt;sup>189</sup> Matthew Perrone, <u>Pro-Painkiller echo chamber shaped policy amid drug epidemic</u>, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic.

 $<sup>^{190}</sup>$  *Id*.

<sup>&</sup>lt;sup>191</sup> <u>HDA History</u>, Healthcare Distribution Alliance, (accessed on September 14, 2017), https://www.healthcaredistribution.org/about/hda-history.

361. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

362. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

363. Defendants paid nearly \$800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

364. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

365. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."<sup>192</sup>

<sup>&</sup>lt;sup>192</sup> See <u>HDMA is now the Healthcare Distribution Alliance</u>, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

366. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed high-level data regarding sales of the opioids they manufactured. And, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

367. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas, year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids that had not been properly investigated or reported by the RICO Defendants.

368. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.<sup>193</sup> On information and belief, the "know your customer" questionnaires informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances are sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

<sup>&</sup>lt;sup>193</sup> <u>Suggested Questions a Distributor should ask prior to shipping controlled substances</u>, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm\_industry/14th\_pharm/levinl\_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. <u>Pharmaceutical Production Diversion: Beyond the PDMA</u>, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product\_diversion\_beyond\_pdma.pdf).

369. The RICO Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012<sup>194</sup> and 117 recommended decision in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.<sup>195</sup>

370. Defendants' scheme had decision-making structure that was driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion, and identify suspicious orders and report them to the DEA.

371. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was proopioid. The Manufacturer and Distributor Defendants did this through their participation in the Pain Care Forum and Healthcare Distributors Alliance.

372. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting suspicious orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no

 <sup>&</sup>lt;sup>194</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
 <sup>195</sup> Id.

basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

- a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;
- b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces, and working groups;
- c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioids prescriptions filled by the Distributor Defendants;
- d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;
- e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing opioids."<sup>196</sup>
- f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;
- g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;
- h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and
- j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

<sup>&</sup>lt;sup>196</sup> Harriet Ryan, et al., <u>More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew</u>, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

373. The scheme devised and implemented by the RICO Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled substances.

# C. PATTERN OF RACKETEERING ACTIVITY.

374. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); and 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment buying selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

## 1. The RICO Defendants Engaged in Mail and Wire Fraud.

375. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

376. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

377. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

378. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

379. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

380. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third

parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme,

including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids;
- c. Defendants' DEA registrations;
- d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;
- e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- f. Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Manufacturers;
- k. Rebates and chargebacks from the Manufacturers to the Distributors;
- 1. Payments to Defendants' lobbyists through the Pain Care Forum;
- m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.
- 381. On information and belief, the RICO Defendants (and/or their agents), for the

purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received)

by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

382. Purdue manufactures multiple forms of prescription opioids, including but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

383. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

384. Cephalon manufactures multiple forms of prescription opioids, including but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants in this jurisdiction.

385. The Distributor Defendants shipped Teva's prescription opioids throughout this jurisdiction.

386. Janssen manufactures prescription opioids known as Duragesic. Janssen manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

387. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

388. Endo manufactures multiple forms of prescription opioids, including but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

389. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

390. Actavis manufactures multiple forms of prescription opioids, including but not limited to: Kadin and Norco, as well as generic versions of the drugs known as Kadian, Duragesic and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants in this jurisdiction.

391. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

392. Mallinckrodt manufactures multiple forms of prescription opioids, including but not limited to: Exalgo and Roxicodone.

393. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

394. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

395. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and that they complied with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

396. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

397. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

398. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants' scheme and common course of conduct was intended to increase or maintain high production quotas for their prescription opioids from which they could profit.

399. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. But, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

400. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

401. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

402. The RICO Defendants hid from the general public, and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities, about the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of a tens of millions of doses of prescriptions opioids into the illicit market.

403. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

404. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

405. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

406. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the RICO Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

407. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

408. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

409. Many of the precise dates of the RICO Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

410. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs. 411. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

412. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

413. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

# 2. The RICO Defendants Manufactured, Sold and/or Dealt in Controlled Substances and Their Crimes Are Punishable as Felonies.

414. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

415. The RICO Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 483(d)(1).

416. Each of the RICO Defendants qualify as registrants under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant

suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

417. Pursuant to the CSA and the Code of Federal Regulations, the RICO Defendants were required to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

418. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

419. For example, The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form-8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the CSA and agreed to pay \$150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.<sup>197</sup>

420. Purdue's experience in Los Angeles is another striking example of Defendants' willful violation of the CSA and Code of Federal Regulations as it relates to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of

<sup>&</sup>lt;sup>197</sup> McKesson, <u>McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement</u> <u>Administration to Resolve Past Claims</u>, About McKesson / Newsroom / Press Releases, (January 17, 2017(), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-dojand-dea-to-resolve-past-claims/.

a pill mill operating out of Los Angeles yet failed to alert the DEA.<sup>198</sup> The LA Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."<sup>199</sup> Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."<sup>200</sup>

421. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt arguing that it ignored its responsibility to report suspicious orders as <u>500 million</u> of its pills ended up in Florida between 2008 and 2012.<sup>201</sup> After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a \$35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida but they had no duty to report it.<sup>202</sup>

<sup>&</sup>lt;sup>198</sup> Harriet Ryan, et al., <u>More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew</u>, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

<sup>&</sup>lt;sup>199</sup> Id.

 $<sup>^{200}</sup>$  Id.

<sup>&</sup>lt;sup>201</sup> Lenny Bernstein & Scott Higham, <u>The government's struggle to hold opioid manufacturers accountable</u>, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/deamallinckrodt/?utm\_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.

<sup>&</sup>lt;sup>202</sup> Id.

422. Plaintiff is informed and believes that the foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the sheer volume of enforcement actions available in the public record against the Distributor Defendants.<sup>203</sup> For example:

423. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

424. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

425. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

426. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

<sup>&</sup>lt;sup>203</sup> Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

427. On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

428. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

429. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

430. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

431. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

432. On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for

violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Santa Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

433. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

434. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

435. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

436. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the

citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

437. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

438. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations would harm Plaintiff by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

439. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

#### D. DAMAGES

440. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

441. Plaintiff's injuries, and those of her citizens, were proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services, social services and first responders' services and expenditures required as a result of the plague of drug-addicted residents.

442. Plaintiff's injuries and those of its citizens were directly caused by the RICO Defendants' racketeering activities.

443. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

444. Plaintiff seeks all legal and equitable relief as allowed by law, including *inter alia* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

#### COUNT III RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1962(d), *et seq.* (Against All Defendants)

445. Plaintiff hereby incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

446. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d) it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

447. Defendants conspired to violate Section 1962(c), as alleged more fully above, by conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

## A. THE OPIOID DIVERSION ENTERPRISE.

448. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the "Opioid Diversion Enterprise."

### **B.** CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

449. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the "Conduct of the Opioid Diversion Enterprise."

#### C. PATTERN OF RACKETEERING ACTIVITY.

450. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set forth above concerning the "Pattern of Racketeering Activity."

### D. DAMAGES.

451. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference.

452. Plaintiff's injuries, and those of her citizens, were proximately caused by the RICO Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services, social services, and first responders' services and expenditures required as a result of the plague of drug-addicted residents.

453. Plaintiff's injuries and those of her citizens were directly caused by the RICO Defendants' racketeering activities.

454. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

455. Plaintiff seeks all legal and equitable relief as allowed by law, including inter alia actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorney's fees and all costs and expenses of suit and pre- and post-judgment interest.

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## COUNT IV NEGLIGENCE AND NEGLIGENT MISREPRESENTATION (Against All Defendants)

456. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

457. Plaintiff seeks economic damages which were the foreseeable result of Defendants' intentional and/or unlawful actions and omissions.

458. Under State law, to establish actionable negligence, one must show in addition to the existence of a duty, a breach of that duty, and injury resulting proximately therefrom. All such essential elements exist here.

459. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs to the State and Plaintiff's Community.

460. Each Defendant had an obligation to exercise due care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in the State and Plaintiff's Community.

461. The existence of a duty depends on the foreseeability of the injury. Each Defendant owed a duty to the Plaintiff and to Plaintiff's Community because the injuries alleged herein was foreseeable, and in fact foreseen, by the Defendants.

462. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

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463. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids, frequently turning to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants.

464. Moreover, Defendants were repeatedly warned by law enforcement of the unlawfulness and consequences of their actions and omissions.

465. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

466. As described above in language expressly incorporated herein, Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable.

467. As described elsewhere in the Complaint in language expressly incorporated herein, Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids to Plaintiff's Community and destinations from which they knew opioids were likely to be diverted into Plaintiff's Community, in addition to other misrepresentations alleged and incorporated herein.

468. As described elsewhere in the Complaint in language expressly incorporated herein, Manufacturer Defendants breached their duties to exercise due care in the business of pharmaceutical manufacturers of dangerous opioids, which are Schedule II Controlled Substances, and by misrepresenting the nature of the drugs and aggressively promoting them for chronic pain for which they knew the drugs were not safe or suitable.

469. The Manufacturer Defendants misrepresented and concealed the addictive nature of prescription opioids and its lack of suitability for chronic pain, in addition to other misrepresentations alleged and incorporated herein.

470. All Defendants breached their duties to prevent diversion and report and halt suspicious orders, and all Defendants misrepresented their compliance with their legal duties.

471. Defendants' breaches were intentional and/or unlawful, and Defendants' conduct was willful, wanton, malicious, reckless, oppressive, and/or fraudulent.

472. The causal connection between Defendants' breaches of duties and misrepresentations and the ensuing harm was entirely foreseeable.

473. As described above in language expressly incorporated herein, Defendants' breaches of duty and misrepresentations bear a causal connection with, and/or proximately resulted in the damages sought herein.

474. The Defendants supplied information to the Plaintiff and its citizens; the Defendants intended for the Plaintiff and its citizens to rely on such information; the information was false; the Defendants failed to use reasonable care or competence in obtaining or communicating the information; the Plaintiff and its citizens relied on such information and had no other or actual means to determine its falsity; was denied the opportunity to investigate; could

not have learned of the true facts by the exercise of reasonable diligence; and such reliance has caused financial damage to the Plaintiff and will continue to do so in the future.

475. Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Defendants' knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than medical, scientific, or industrial channels. However, Defendants breached their duties to monitor for, report, and halt suspicious orders, breached their duties to prevent diversion, and, further, misrepresented what their duties were and their compliance with their legal duties.

476. Defendants' unlawful and/or intentional actions constitute negligence under State law.

477. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

478. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

# COUNT V NEGLIGENCE PER SE (Against All Defendants)

479. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

480. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

481. The North Carolina controlled substances laws and regulations are public safety laws. Each Defendant had a duty under, *inter alia*, these laws maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Plaintiff and Plaintiffs' Community are within the class of persons intended to be protected by these laws.

482. Defendants' actions and omissions in violation of the law constitute negligence per se.

483. Defendants' actions and omissions were intentional and/or unlawful, and Defendants acted with actual malice.

484. It was foreseeable that the breach of duty described herein would result in the economic damages for which Plaintiff seeks recovery.

485. As described above in language expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

486. As described above in language expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bear a causal connection with, and proximately resulted in, harm and damages sought by the Plaintiff.

487. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence per se. Plaintiff does not seek damages for the

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wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

488. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

# COUNT VI DECEPTIVE TRADE PRACTICES COMMON LAW AND NORTH CAROLINA GENERAL STATUTES 75-1 et seq. (Against All Defendants)

489. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

490. Plaintiff asserts this action on its behalf and on behalf of the Dare County public.

491. Defendants violated N.C. Gen. Stat. 75-1 et seq., because they engaged in deceptive

trade practices in this State. Defendants' actions also violated North Carolina common law.

492. Defendants committed and are committing repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of, and in or affecting, commerce.

493. Each Defendant failed to report suspicious orders of and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

494. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused an opioid and heroin plague and epidemic in the State and Plaintiff's Community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

495. The Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

496. The Defendants failed to disclose the material facts that *inter alia* they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

497. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

498. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

499. The Manufacturer Defendants engaged in an improper and unlawful rebate scheme to unfairly target specific markets and increase sales volume.

500. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which tended to deceive and/or did in fact deceive.

501. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

502. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed

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material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

503. Defendants' unfair, deceptive, and unconscionable representations, concealments, and omissions were reasonably calculated to deceive the State, the public, Plaintiff's Community, and Plaintiff.

504. As described more specifically above, Defendants' representations, concealments, and omissions constitute a willful course of conduct which continues to this day.

505. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Manufacturer and Distributor Defendants' intentional and/or unlawful actions and omissions.

506. Defendants' actions and omissions in the course of marketing, selling, and distributing prescriptions opioids constituted deceptive trade practices under applicable law.

507. It is unlawful to represent that goods or services have sponsorship, approval, characteristics, uses, or benefits that they do not have. It is unlawful to represent that goods are of a standard, quality, or grade if they are of another.

508. Defendants have engaged in repeated and willful unfair or deceptive acts or practices, and unconscionable trade practices, in the conduct of commerce in this State and in Plaintiff's Community.

509. Each Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs.

510. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' manufacturing, marketing, sales, and distribution practices unlawfully caused an

opioid and heroin plague and epidemic in the State and Plaintiff's Community. Each Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

511. The Defendants also omitted material facts, causing confusion or misunderstanding as to approval or certification of goods or services.

512. The Defendants failed to disclose the material facts that *inter alia* they were not in compliance with laws and regulations requiring that they maintain a system to prevent diversion, protect against addiction and severe harm, and specifically monitor, investigate, report, and refuse suspicious orders. But for these material factual omissions, Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

513. As alleged herein, each Manufacturer Defendant wrongfully represented that the opioid prescription medications they manufactured, marketed, and sold had characteristics, uses, or benefits that they do not have.

514. The Manufacturer Defendants also wrongfully misrepresented that the opioids were safe and effective when such representations were untrue, false, and misleading.

515. The Manufacturer Defendants also used exaggeration and/or ambiguity as to material facts and omitted material facts, which had a tendency to deceive and/or did in fact deceive.

516. Because of the dangerously addictive nature of these drugs, which the Manufacturer Defendants concealed and misrepresented, they lacked medical value, and in fact caused addiction and overdose deaths; therefore, Defendants' sales and marketing of opioids constituted a violation of State law.

517. The Manufacturer Defendants made deceptive representations about the use of opioids to treat chronic non-cancer pain. Each Manufacturer Defendant also omitted or concealed material facts and failed to correct prior misrepresentations and omissions about the risks and benefits of opioids. Each Defendant's omissions rendered even their seemingly truthful statements about opioids deceptive.

518. Defendants acted intentionally and/or unlawfully.

519. Defendants' actions were directed toward the Plaintiff and proximately caused injury to Plaintiff, as alleged herein.

520. Defendants' actions affected commerce and constituted commercial activity.

521. Plaintiff seeks all damages pursuant to N.C. Gen. Stat. § 75-1, *et seq.*, tabled, and attorneys fees, for injuries sustained because of Defendants' violation of statutory and common law, and all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

522. Defendants' violations of Federal law, regulations, and statutes constitute *per se* violations of N.C. Gen. Stat. § 75-1, *et seq*.

## COUNT VII CIVIL CONSPIRACY (Against All Defendants)

523. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

524. As set forth herein, Defendants engaged in an agreement and a civil conspiracy to create an absolute public nuisance in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

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525. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's Community.

526. Distributor and Manufacturer Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

527. The Manufacturer Defendants further unlawfully marketed opioids in the State and Plaintiffs' Community in furtherance of that conspiracy, or if they were performing lawful acts, did them in an unlawful manner.

528. Defendants' conspiracy and acts in furtherance thereof are alleged in greater detail earlier in the complaint, including, without limitation, in Plaintiff's racketeering allegations. Such allegations are incorporated herein.

529. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

530. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonably or lawful excuse.

531. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

532. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' civil conspiracy. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

533. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

## COUNT VIII FRAUD AND FRAUDULENT MISREPRESENTATION (Against All Defendants)

534. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth here, and further alleges as follows.

535. Defendants violated their general duty not to actively deceive, and have made knowingly false statements and have omitted and/or concealed information which made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

536. As alleged herein, Defendants made false statements regarding their compliance with state and federal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

537. As alleged herein, the Manufacturer Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

538. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, and persons on whom Plaintiff relied.

539. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids for persons in Plaintiff's Community, were made with the intent to deceive, and did in fact deceive these persons, Plaintiff, Plaintiff's Community and the physicians.

540. Plaintiff, Plaintiff's Community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

541. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

542. Due to Defendants' concealment and tortious acts, Plaintiff could not have learned of the true facts by exercise of reasonable diligence.

543. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

544. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

545. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Distributor Defendants, attorney fees and costs, and pre- and post-judgment interest.

## **PUNITIVE DAMAGES**

546. Plaintiff re-alleges all paragraphs of this Complaint as if set forth fully herein.

547. By engaging in the above-described unfair acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm.

548. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the State and Plaintiff's Community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence, and the safety of the community, and an award of punitive damages is appropriate, as punishment and a deterrence.

549. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

## I. <u>RELIEF</u>

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

550. Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants, jointly and severally;

551. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries,

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and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary or permanent injunction;

552. Ordering that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

553. Ordering Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

554. Awarding actual damages, treble damages, punitive damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit, including pursuant to Plaintiff's racketeering claims;

555. Awarding the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and other treatments for patients suffering from opioid-related addiction (Naloxone) or disease (Sexually Transmitted Diseases and Hepatitis C), including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic; and other damages as outlined herein or to be determined.

556. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

557. Granting the Plaintiff:

a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

b. Pre-judgment and post-judgment interest; and,

c. All other relief as provided by law and/or as the Court deems appropriate and just.

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Dated: May , 2018

Respectfully Submitted,

DARE COUNTY, By Counsel

<u>/s/</u>\_\_\_\_\_

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**Consent Agenda** 

# Description

- 1. Approval of Minutes (04.16.18 & Budget Workshop)
- 2. Detention Center Willo Service Contract for Mechanical Doors
- 3. Detention Center Thyssen Krupp Service Contract for Elevator

# **Board Action Requested**

Approval

## **Item Presenter**

County Manager, Robert Outten



Approval of Minutes

# Description

The Board of Commissioners will review and approve their previous Minutes, which follow this page.

# **Board Action Requested**

Approve Previous Minutes

## **Item Presenter**

County Manager, Robert Outten



# COUNTY OF DARE, NORTH CAROLINA

District 1: Roanoke Island & Mainland; District 2: Nags Head, Colington, Kill Devil Hills; District 3: Kitty Hawk, Southern Shores, Duck; District 4: Chicamacomico, Avon, Buxton, Frisco, Hatteras; District 5: At Large

Regularly scheduled Board meetings are videotaped and can be viewed at www.darenc.com

## MINUTES

## DARE COUNTY BOARD OF COMMISSIONERS MEETING

Dare County Administration Building, Manteo, NC

5:00 p.m., April 16, 2018

Commissioners present:	Chairman Robert Woodard, Vice Chairman Wally Overman Steve House, Rob Ross, Jim Tobin, Danny Couch
Commissioners absent:	Jack Shea
Others present:	County Manager/Attorney, Robert Outten Deputy County Manager/Finance Director, David Clawson Public Information Officer, Dorothy Hester Clerk to the Board, Gary Lee Gross

A full and complete account of the entire Board of Commissioners meeting is archived on a video that is available for viewing on the Dare County website www.darenc.com.

Chairman Woodard called the meeting to order at 5:00 p.m. He invited Rev. David Morris from the Unitarian Universalist Congregation of the Outer Banks to share a prayer, and then he led the Pledge of Allegiance to the flag. It was announced that Commissioner Shea had an excused absence from the meeting.

# ITEM 1 – OPENING REMARKS – CHAIRMAN'S UPDATE

Following is a brief outline of the items mentioned by Chairman Woodard during his opening remarks, which can be viewed in their entirety in a video on the Dare County website –

- Chairman Woodard reported on Governor Cooper's recent appearance in Dare County where the Governor expressed a desire to improve education in North Carolina, addressed the opioid crisis, and helped raise awareness about dementia.
- A summary of the Board's Budget Workshop was given and the Chairman announced that one more Budget Workshop will be held in order for the Board to give budget direction to the County Manager.
- The Chairman asked everyone to keep the Bush family in their prayers regarding the medical condition of former First Lady Barbara Bush.

# **ITEM 2 – PUBLIC COMMENTS**

The Manager outlined the procedure for making public comments in Manteo and via the video link to the Fessenden Center in Buxton. Following is a brief summary of citizen remarks, which can be viewed in their entirety in a video on the Dare County website –

The following comments were made in Manteo -

- Jack Huh explained his background working with dogs and described the benefits of canine agility training. He said he is willing to build the equipment and donate it to the Roanoke Island Dog Park noting that liability issues related to the use of agility equipment need to be addressed. Mr. Huh provided handout material showing how agility equipment is used along with a sample liability waiver and proposed rules for the Roanoke Island Dog Park.
- 2. Judy Williams thanked Commissioners for the Roanoke Island Dog Park, which she described as a huge success. She pointed out that there are unfinished issues related to the fencing of the Dog Park. Mrs. Williams asked when the site will have its official opening day and whether the users would be able to express their concerns about the park's rules and regulations. She also noted that handicapped parking signs are needed at the Roanoke Island Dog Park.

There were no comments made in Buxton -

Following Public Comments, Commissioners and the County Manager addressed items that were raised about the Dog Park including fencing, liability issues, and where to locate the canine agility equipment. It was noted that the agility equipment needs to be movable in order to accommodate mowing and special event parking. The Manager gave an update on fencing work that remains to be done and efforts to provide shade and water. Mr. Outten explained that the rules for the Roanoke Island Dog Park will be the same as those at the Kitty Hawk Dog Park and noted that the County's Parks and Recreation Director is willing to talk about the rules and listen to community input. The Manager clarified that decisions about the operation of the Dog Park will be handled at the level of the Parks and Recreation Department and not at the Board of Commissioners level. He added that the County will give ample notice about the official opening day of the Dog Park so that people will have time to get their dogs registered and complete the release forms. Chairman Woodard asked that Parks and Recreation staff be onsite when the fencing contractor is at the Dog Park so that the fencing issues can be properly addressed and completed in a timely fashion.

ITEM 3 – TOURISM BOARD REQUEST CONSENT FOR FIREWORKS GRANT AWARDS

Lee Nettles, Executive Director of the Outer Banks Visitors Bureau, requested \$46,000 in expenditures from the Short Term Restricted Fund for fireworks awards to the following – Avon Property Owners Assoc. \$10,750 Town of Kill Devil Hills \$11,750 Town of Manteo \$11,750 Town of Nags Head \$11,750

# **MOTION**

Vice Chairman Overman motioned to approve the awards in the amount of \$46,000. Commissioner House seconded the motion. VOTE: AYES unanimous

## ITEM 4 – HEALTH INSURANCE FOR FY 2018-2019

The County Manager provided background information about the health insurance plan for Dare County employees for the upcoming fiscal year. He noted that there are two plans available that will have an increase of 7% for FY 2018-2019.

## MOTION

Commissioner Tobin motioned to approve health insurance plan for FY18-19 as presented. Commissioner House and Vice Chairman Overman seconded the motion. VOTE: AYES unanimous

## **ITEM 5 – CONSENT AGENDA**

The Manager announced the items as they were visually displayed in the meeting room. **MOTION** 

Commissioner Couch motioned to approve the Consent Agenda:

- 1) Approval of Minutes (04.03.18) (Att. #1)
- 2) Appointment of Firefighter's Relief Board Member Hatteras Volunteer Fire Dept.
- 3) Tax Collector's Report

Commissioner House seconded the motion.

VOTE: AYES unanimous

## ITEM 6 – COMMISSIONERS' BUSINESS & MANAGER'S/ATTORNEY'S BUSINESS

Commissioners and the County Manager frequently make extensive remarks, which can be viewed in their entirety in a video on the Dare County website. Following is a brief summary outline of the items mentioned by Commissioners during this segment –

Commissioner House

- Reported on a good Juvenile Crime Prevention Council (JCPC) Workshop event. He
  provided information about a special program, known as ASEP, which stands for All
  Summer Enrichment Program. Commissioner House explained the merits of the ASEP
  program and how it provides excellent supervision in a proper environment and
  encouraged people to participate.
- Commissioner House presented the Pet of the Week video showcasing an animal available for adoption at the Dare County Animal Shelter.

Vice Chairman Overman – no additional comments

Commissioner Couch - no additional comments

## Commissioner Tobin

 Reported on the latest meeting of the Oregon Inlet Task Force including dredging information from the Army Corps of Engineers. He briefed the Board on a suggestion he made to help the dredging effort increase its efficiency by utilizing a crew boat to shuttle staff to and from the site.

- An update was given on the Dare County Older Adult Services Board meeting, where appreciation was expressed for the new flooring that was installed. A reminder was given about the upcoming Dare County Senior Games.
- Commissioner Tobin informed the Board that he toured both Spring Arbor and Peak Resources on behalf of the Community Advisory Council and reported that he received one complaint, which was addressed to the Regional Ombudsman.
- Voiced excitement about young people getting involved with the Cooperative Extension 4-H program and noted that the program has a new 4-H Agent for Dare County.
- Commissioner Tobin reported on a meeting involving Senator Cook, Representative Boswell, and the Park Service Superintendent where stakeholders were able to discuss ideas for stabilizing Bodie Island including possible sand bypassing systems.

# Commissioner Ross

- Reported that the Albemarle Commission is moving forward with plans for their new offices, which will be done as a leased facility.
- Commissioner Ross reported on the recent Nags Head Community Watch event where school safety was discussed. He said it was reassuring to hear that there are Resource Officers in every Dare County school who are familiar with the students and staff.
- Provided details about the upcoming graduation ceremony for Manteo High School.

<u>Chairman Woodard</u> – no additional comments

# MANAGER'S/ATTORNEY'S BUSINESS

1. The County Manager reported that there have been multiple problems with the firm that currently provides billing services for the Emergency Medical Services Department. He recommended addressing this problem by contracting with a different vendor and reported on talks that have been held with a firm known as Colleton. Mr. Outten presented a 3-year agreement with Colleton and noted that although the new firm charges more for their services, they have a higher rate of recovery, which should offset it. He said in order to terminate the agreement with the existing vendor, the County needs to give notice before the end of the month.

# **MOTION**

Vice Chairman Overman motioned to terminate the agreement with the current vendor and enter into a 3-year agreement with Colleton as outlined by the County Manager. Commissioner House seconded the motion. VOTE: AYES unanimous

2. Mr. Outten informed the Board of discounts that are available on the purchase of ambulances, cots, and cot fasteners if the County provides a Letter of Intent to the vendor regarding purchases that are already planned for the next fiscal year. He asked the Board for authority to send Letters of Intent.

# <u>MOTION</u>

Commissioner House motioned to authorize Letters of Intent as outlined by the Manager. Commissioner Ross seconded the motion.

VOTE: AYES unanimous

Public Information Officer Dorothy Hester noted that Dare County is one of four school systems in the State of North Carolina that has Resource Officers in every school. Ms. Hester also outlined upcoming meetings that the Planning Department has organized to gather public input on the Dare County Land Use Plan. Details were also provided about the upcoming grand opening of the Skate Park in Rodanthe.

Prior to adjournment, Chairman Woodard thanked David Clawson and Sally DeFosse for the information that was presented at today's Budget Workshop.

At the conclusion of the meeting, Chairman Woodard asked for a motion to adjourn. MOTION Commissioner Couch motioned to adjourn the meeting. Commissioner House seconded the motion. VOTE: AYES unanimous

At 5:52 p.m., the Board of Commissioners adjourned until 9:00 a.m., May 7, 2018.

Respectfully submitted,

[SEAL]

By: \_\_\_\_\_\_Gary Lee Gross, Clerk to the Board

APPROVED:

By: \_\_\_\_ Robert Woodard, Chairman Dare County Board of Commissioners



# COUNTY OF DARE, NORTH CAROLINA

District 1: Roanoke Island & Mainland; District 2: Nags Head, Colington, Kill Devil Hills; District 3: Kitty Hawk, Southern Shores, Duck; District 4: Chicamacomico, Avon, Buxton, Frisco, Hatteras; District 5: At Large

## MINUTES

# DARE COUNTY BOARD OF COMMISSIONERS

## SPECIAL MEETING

To conduct a workshop on the upcoming fiscal year budget;

Dare County Administration Building, Room #238, Manteo, NC

# 1:00 p.m., April 16, 2018

Commissioners present:	Chairman Robert Woodard, Vice Chairman Wally Overman Steve House, Rob Ross, Jim Tobin, Danny Couch
Commissioners absent:	Jack Shea
Others present:	County Manager/Attorney, Robert Outten Deputy County Manager/Finance Director, David Clawson Public Information Officer, Dorothy Hester Clerk to the Board, Gary Gross

Chairman Woodard called the meeting to order at 1:02 p.m. He asked Sheriff Doughtie to offer an opening prayer and then led the group in the Pledge of Allegiance to the flag.

## **BUDGET WORKSHOP**

The County Manager and the Finance Director presented a comprehensive packet of budget information that included revenue changes for the 2019 fiscal year. A step-by-step analysis was given of the budget requests that have been submitted by Dare County departments and the impact that each one would have on the planned 2019 budget. Mr. Outten commended Department Heads for effectively managing their budgets and noted that only a small list of budget requests were submitted.

## RECESS: 3:21 p.m. – 3:36 p.m.

During the Budget Workshop, there was discussion of the feasibility of the County possibly matching up to 2% of an employee's contribution into their 401k account. Chairman Woodard polled Department Heads about this and feedback was positive.

The County Manager explained that the material being presented at today's workshop represents the budget that will be formally submitted to the Board at a future meeting unless Commissioners tell him otherwise. The Chairman polled Board Members on whether another Budget Workshop was necessary and it was determined that time was needed for Commissioners to review today's material in order to provide budget guidance to the County Manager.

The Chairman said a date will be determined for the next Budget Workshop and thanked staff for their participation before asking for a motion to adjourn. **MOTION** 

Commissioner House motioned to adjourn the meeting. Commissioner Ross seconded the motion. VOTE: AYES unanimous

At 4:23 p.m., the Board of Commissioners adjourned the Budget Workshop.

Respectfully submitted,

[SEAL]

By: \_\_\_\_\_ Gary Lee Gross, Clerk to the Board

APPROVED: \_\_\_\_\_

Robert Woodard, Chairman



Service Contract Review

# Description

Board of Commissioners to review Willo service contract. (mechanical doors)

# **Board Action Requested**

Review and approve contract.

# **Item Presenter**

Allen Moran



Willo Products Company, Inc. P.O. Box 1349 Decatur, AL 35602 Phone: 256-353-7161, Fax: 256-350-8436

# **SERVICE AGREEMENT**

January 29, 2018

To: Dare County Jail 1044 Driftwood Drive, Box 1000 Manteo, NC 27954

Willo Products Company, Inc., agrees to provide the services as described herein set forth in Item III.

## I - TERMS

This Service Agreement between **Willo Products Co., Inc** (Willo) and **Dare County Jail** (Facility or Purchaser) is for a period of <u>Sixty (60) Months</u>. It will become effective on **April 1, 2018** and continue until **March 31, 2022**. The Equipment to be serviced is listed in paragraph II and the SERVICE to be performed is listed in paragraph III below. Service to equipment that is not included in item II EQUIPMENT TO BE SERVICED can be obtained at an extra to this contract as described in item V – ADDITIONAL SERVICE NEEDS.

# II – EQUIPMENT TO BE SERVICED

- Forty-Eight (48) Folger Adam Series 10 Locks
- Four (4) Folger Adam Series 80 Locks
- Five (5) Folger Adam Series 52 Locks
- Seven (7) Folger Adam Series 120 Locks
- Four (4) Folger Adam Series 80-4BL Locks
- Ten (10) Brinks Series 3020 Locks
- Sixty-Two (62) Willo Products Sliding Door Operators
- Six (6) Willo Products Door Control Consoles
- One Hundred Eight (108) Willo Products Door Position Switches (DPS)

# III – SERVICE

- Service Tune-Up, according to the below schedule to include the following...
- Quarterly High Traffic Doors
- Semi-Annually Medium Traffic Doors

## SERVICE AGREEMENT Page 2 of 4

- Annually Cell Doors and Remaining Detention Doors
  - Complete removal of all transom covers, make all necessary adjustments to bring the devices up to factory standards, vacuum all transoms, and lubricate all moving points in the devices.
  - Provide all labor necessary to replace any and all worn parts during the Tune-Up, test the device for smooth operation, and check all electrical connections within the sliding device.
  - Reinstall the transom covers and assure they are securely in place.
  - Remove electric lock covers, clean when necessary, check and replace worn parts, lubricate, make roller bolt assembly adjustments to assure proper dead-locking, adjust indication switches, check for proper operation, inspect electrical connections, and reinstall lock covers
  - Check mechanical locks for correct operation and lubricate as required.
  - Check door control consoles for proper operation and indication.
     Remove and replace worn switches as necessary. Remove and replace indication lamps as necessary. Inspect electrical connections.
  - Inspect and repair DPS as necessary.
- Four (4) scheduled service calls, one every three months.

**Emergency Visit**: Emergency visit available at facility request. Discounted rates for Travel, Labor and Per Diem. Cost per visit would be \$3939.00 (Three Thousand Nine Hundred and Thirty-nine dollars)

# IV – PARTS

In an effort not to escalate the price we cover the labor for replacing any parts required but we do not include the cost of the parts. We will supply any parts needed at a <u>10% discount</u>. The cost of any parts that are needed will be added to this contract and billed upon completion of the service. The Facility will receive a 10% discount on any additional parts ordered during the term of this Service Agreement.

# V – ADDITIONAL SERVICE NEEDS

Service that is not covered directly under this Service Agreement may be obtained at a reduced hourly rate of \$75.50 per hour, 7:00 AM through 3:30 PM, Monday through Friday. If overtime or weekend work is requested it will be at a cost of \$150.00 per hour. If the additional work exceeds four (4) hours a daily per-diem rate will be charged at \$213 per day for each man working.

# <u>VI – COST</u>

## SERVICE AGREEMENT Page 3 of 4

The above services shall be provided for the sum of \$2,532.00 (Two Thousand, Five Hundred Thirty-two Dollars) per month for a period of 60 consecutive months beginning April 1, 2018 for the services provided by this agreement.

## VII – PAYMENT TERMS

Payment is to be made monthly, at the beginning of each month of the contract term. Terms are Net 15 from date of billing.

## VIII – FACILITIES

Purchaser will furnish suitable working facilities and electric power to accommodate necessary service equipment (110 or 220 VAC) as required, including ready access to security areas without experiencing delays. Willo Products shall have full access to the equipment in order to provide the services under this agreement. The facility will provide escorts if required at no additional charge to Willo.

# IX - CHANGES MADE TO EQUIPMENT

Any changes or relocation in the equipment or devices or attachments made by Purchaser, between service trips made by Willo, may result in added cost to this contract. Any equipment found to have safety hazards shall be avoided and, upon written notice to the purchaser, such safety hazards shall be promptly corrected at purchaser's expense prior to Willo performing service to that equipment.

# X - EXCLUSIONS

- Wire, conduit, or wiring in conduit
- Service to parts and equipment not listed in paragraph II above.
- Bond
- Retainage
- Our price does not include sales, use, excise, value added, or similar taxes or licenses required by your municipality, county, or state. Consequently, in addition to the price specified here in, Purchaser shall pay, or reimburse Willo for the gross amount of any such costs applicable to the sale for furnishing of the services or products here in. In lieu thereof, Purchaser may provide Willo with tax exemption evidence acceptable to taxing authorities.

# XI - EXTENSION AND/OR CANCELLATION OF AGREEMENT

This Service Agreement has the option to be extended for an additional Sixty (60) months with up to a 10% price increase provided the Facility or Willo gives notice within the final 12 months of the agreement, but no later than 30 days prior to the end of the agreement.

## SERVICE AGREEMENT Page 4 of 4

- Should the Facility wish to extend the Agreement they will give Willo written notice of their desires prior to the final 30 days of the Agreement.
- Should Willo wish to change the price or not extend the Agreement they will give the Facility written notice prior to the final 30 days of the Agreement.

## XII – COMPLETE AGREEMENT

This Agreement contains the complete agreement between the parties, and no modifications, amendment, recession, waiver, or other change will be binding on Willo or the Facility unless assented to in writing by both parties. Any oral or written representation, warranty, course of dealing or trade usage not contained or referenced here in, shall not be binding on Willo. This proposal is good for sixty days.

# **XIII - ACCEPTANCE OF AGREEMENT**

# WILLO PRODUCTS COMPANY, INC.

BY: Mac E Havin

NAME: Marc E Harris

TITLE: Sr. Inside Sales Rep

DATE: April 25,2018

BY:	
Signature	
NAME:	
TITLE:	
DATE:	

PURCHASER

"This instrument has been preaudited in the manner required by the Local Government End of Agreement Budget and Fiscal Control Act."

Sally Detoool 04/26/2018



Service Contract Review

# Description

Board of Commissioners to review Thyssen Krupp service contract and repair agreement. (elevator)

# **Board Action Requested**

Review and approve contract.

# **Item Presenter**

Allen Moran

Purchaser:	Dare County Detention Center 1044 Driftwood Dr Manteo, NC 27954-9349
	Hereinafter referred to as "Purchaser", "you", and "your".
By:	ThyssenKrupp Elevator Corporation 1244 Executive Blvd Bldg A Ste 103 Chesapeake, VA 23320 Phone: 757-547-9025 Fax: 866-523-2357 www.thyssenkruppelevator.com

Hereinafter referred to as "ThyssenKrupp Elevator Corporation", "ThyssenKrupp Elevator", "we", "us" and "our".

# PLATINUM SERVICE AGREEMENT

ThyssenKrupp Elevator agrees to maintain Purchaser's elevator equipment described below in accordance with this agreement. We will endeavor to provide a comprehensive maintenance program designed to protect your investment and maximize the performance, safety, and life span of the elevator equipment to be maintained.

Equipment To Be Maintained					
Building Name	Building Location	Manufacturer	Type Of Unit	Unit ID	# Of Stops
Dare County Detention Center	1044 Driftwood Dr	Dover	Hydraulic	US233648	2



# **ThyssenKrupp Elevator Americas**

## Preventative Maintenance Program

We will service your equipment described in this agreement on a regularly scheduled basis. These service visits will be performed during normal business working days and hours, which are defined as Monday through Friday, 8:00 AM to 4:30 PM (except scheduled holidays). All work performed before or after normal business working days and hours shall be considered "Overtime".

ThyssenKrupp Elevator will perform the following services:

- Examine your elevator equipment for optimum operation. Our examination, lubrication and adjustment will cover the following components of your elevator system:
  - o Control and landing positioning systems
  - o Signal fixtures
  - o Machines, drives, motors, governors, sheaves, and wire ropes
  - o Power units, pumps, valves, and jacks
  - o Car and hoistway door operating devices and door protection equipment
  - o Loadweighers, car frames and platforms, and counterweights
  - o Safety mechanisms
- Lubricate equipment for smooth and efficient performance
- Adjust elevator parts and components to maximize performance and safe operation

### **Full Coverage Parts Repair and Replacement**

ThyssenKrupp Elevator will provide full coverage parts repair and/or replacement for all components worn due to normal wear, unless specifically excluded in the "Items Not Covered" or "Other Conditions" provisions herein. We maintain a comprehensive parts inventory to support our field operations. All replacement parts used in your equipment will be new or refurbished to meet the quality standards of ThyssenKrupp Elevator. Most specialized parts are available within 24 hours, seven days a week. We will relamp all signals as required (during regularly scheduled visits).

### Maintenance Control Program

ThyssenKrupp Elevator performs service in accordance with A17.1 – 2010 / CSA B44-10. Section 8.6 of the code requires the unit owner to have a Maintenance Control Program (MCP), ThyssenKrupp's MCP meets or exceeds all requirements outlined in Section 8.6. The Maintenance Control Program includes ThyssenKrupp Elevator's Maintenance Tasks & Records documentation which shall be used to record all maintenance, repairs, replacements and tests performed on the equipment and is provided with each unit as required by code. ThyssenKrupp Elevator also provides per Section 8.6 of the code, a maintenance tasks procedures manual with each unit; TKE calls this manual the BEEP Manual, or Basic Elevator, Escalator Procedures Manual. We do not perform any tests unless such tests are specifically listed as included elsewhere in this agreement.

### Quality Assurance

To help increase elevator performance and decrease downtime, our technicians utilize the latest industry methods and technology available to us for your specific brand of elevator. They will be equipped with our tools, documentation and knowledge to troubleshoot your unique system, as well as access to a comprehensive parts replacement inventory system.

Behind our technicians is a team devoted to elevator excellence. Technicians are supported around the clock by a team of engineers and field support experts. Our North American technical support facilities continuously research advancements in the industry and in your equipment. Also, our internal quality control program ensures optimum and reliable operation of your elevator equipment.

To assure that quality standards are being maintained, we may conduct periodic field quality audit surveys. Your

Elevator Maintenance Agreement TK 11/11 2018-326593 - ACIA-1EAVS11

dedicated ThyssenKrupp Elevator representative will be available to discuss your elevator needs with you in all aspects of service and modernization. In addition, you may receive recommendations for upgrades that will also provide you with budget options designed to enhance the appearance, performance and safety of or meet Code requirements for your equipment over time.

## Service Requests During Normal Working Days and Hours

Service requests are defined as any request for dispatch of our technician to the location of the equipment covered in this agreement from one or more of the following: you or your representative, the building or building's representative, emergency personnel, and/or passengers through the elevator's communication device and/or from Vista Remote Monitoring through the elevator's communication line. Service requests include minor adjustments and response to emergency entrapments that can be accomplished in two hours or less (excluding travel time) and do not include regularly scheduled maintenance visits.

We will respond to service requests during normal business working days and hours, as defined above, at no additional charge.

### **Overtime Service Requests**

On all overtime service requests, we will absorb straight time costs for labor, and you will be responsible for the difference between the straight time costs and overtime costs for labor. Labor costs include travel time, travel expenses, and time spent on the job. Overtime service requests are performed before or after normal business working days and hours.

### Cloud Based Remote Monitoring Service

thyssenkrupp Elevator reserves the right to install new remote-monitoring devices on your elevators (each a "Device"). Each Device collects elevator signal output (i.e., cycle counters, event counters) (the "Raw Data") and transfers it into our cloud-based IoT (Internet of Things). The data is then analyzed by us to assist thyssenkrupp in anticipating maintenance needs on your equipment. Purchaser authorizes thyssenkrupp to install the Devices and, upon termination of the service agreement, to remove them from the premises if we elect to do so. thyssenkrupp shall be the sole owner of the Devices and the data communicated to us. The Devices shall not become fixtures, and are intended to reside where they are installed and should not be accessed, tampered with, or relocated. thyssenkrupp may remove the Devices and cease all data collection and analysis at any time. If the service agreement between thyssenkrupp and Purchaser is terminated for any reason, thyssenkrupp will automatically deactivate the data collection, terminate the device software and destroy all raw data previously received. The Devices installed by thyssenkrupp contain trade secrets belonging to us, and are installed for the use and benefit of our personnel only. Purchaser agrees not to permit Purchaser personnel or any third parties to use, access, copy, or reverse engineer the Devices.

### □ Service History Website:

This agreement includes Premium access to ThyssenKrupp Elevator's website in accordance with the following terms and conditions. During the term of this Agreement, ThyssenKrupp Elevator agrees to provide Purchaser with a user name and password to ThyssenKrupp Elevator's website for access to maintenance and service call data generated following the effective date of this Agreement. Purchaser shall, at its sole cost, provide and ensure the functioning integrity of its own hardware, software and internet connection necessary to access the website. By executing this Agreement, Purchaser acknowledges that any work performed by ThyssenKrupp Elevator modernization and/or construction personnel may not be included or accessible on the website. ThyssenKrupp Elevator reserves the right to restrict access to the website if any of Purchaser's accounts with ThyssenKrupp Elevator has an outstanding unpaid balance greater than 30 days or in the event of anticipated or pending litigation of any kind.

THE WEBSITE IS PROVIDED TO CUSTOMER "AS IS" AND WITH ALL FAULTS AND DEFECTS WITHOUT WARRANTY OF ANY KIND. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THYSSENKRUPP ELEVATOR EXPRESSLY DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE WITH RESPECT TO THE WEBSITE

INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TILE AND NON-INFRINGEMENT, AND WARRANTIES THAT MAY ARISE OUT OF COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OR TRADE PRACTICE. WITHOUT LIMITATION TO THE FOREGOING, THYSSENKRUPP ELEVATOR PROVIDES NO WARRANTY OR UNDERTAKING, AND MAKES NO REPRESENTATION OF ANY KIND THAT THE CP WILL BE ACCESSIBLE TO CUSTOMER, ACHIEVE ANY INTENDED RESULTS, MEET CUSTOMER'S REQUIREMENTS, OPERATE WITHOUT INTERRUPTION, MEET ANY PERFORMANCE OR RELIABILITY STANDARDS OR BE ERROR FREE OR THAT ANY ERRORS OR DEFECTS CAN OR WILL BE CORRECTED. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW IN NO EVENT WILL THYSSENKRUPP ELEVATOR OR ITS AFFILIATES, BE LIABLE TO THE CUSTOMER OR ANY THIRD PARTY FOR ANY USE, INTERRUPTION, DELAY OR INABILITY TO USE THE WEBSITE OR FOR THE ACT OF ANY THIRD PARTY INCLUDING THE INCORPORATION OF A VIRUS, SPYWARE OR ANY OTHER MALICIOUS PROGRAMS.

## ☑ <u>ThyssenKrupp Communications®</u> (Check box if included)

ThyssenKrupp Communications is ThyssenKrupp Elevator's 24-hour telephone monitoring and emergency call service. Our representatives are trained to handle elevator calls and they can assess the situation and quickly dispatch a technician when necessary. If needed, they can stay on the line to reassure a stranded passenger that help is on the way. ThyssenKrupp Communications maintains digital recordings and computerized records of the time, date, and location of calls received and action taken for the benefit of passengers and building owners. Special considerations regarding ThyssenKrupp Communications are set forth below.

Through its centralized ThyssenKrupp Communications call center, ThyssenKrupp Elevator will provide 7 days per week, 24 hours per day, 365 days per year dispatching service for calls placed by Purchaser after normal business working days and hours to the local ThyssenKrupp Elevator branch office and telephone monitoring on all elevator(s) maintained under this Agreement that have operational telephone equipment capable of placing a call to that call center. Depending on the nature of the call and circumstances, ThyssenKrupp Elevator's operators can call one or more of the following: Purchaser's Designated Contacts set forth in Section 2 below; Local Emergency Services at phone numbers provided by Purchaser in Section 3 below; and/or a local ThyssenKrupp Elevator service technician to be dispatched to the location of the equipment.

Purchaser hereby acknowledges that as a condition precedent to ThyssenKrupp Elevator's placement of calls to Purchaser's Designated Contacts and any Local Emergency Services under this Agreement, Purchaser must first complete Sections 1 and 2 below. Purchaser further acknowledges that it is Purchaser's sole responsibility to advise ThyssenKrupp Elevator immediately in writing of any changes to the information contained in those two (2) sections during the term of this Agreement. Purchaser acknowledges that no revision to that information will be made without ThyssenKrupp Elevator first receiving such request in writing from Purchaser's authorized representative.

Under those circumstances where ThyssenKrupp Elevator is unable to reach Purchaser's Designated Contacts set forth in Section 2 below, Purchaser hereby gives ThyssenKrupp Elevator express permission to dispatch a ThyssenKrupp Elevator service technician to the location of the equipment at Purchaser's expense in accordance with ThyssenKrupp Elevator's applicable billing rates. Purchaser further agrees that ThyssenKrupp Elevator does not assume any duty or responsibility to advise any caller, regardless of his or her location within or outside the elevator, to take or not take any specific action resulting from a medical or other emergency or any other situation including, but not limited to, entrapment of persons, evacuation, repair or return to service of any equipment.

In the event that a ThyssenKrupp Elevator call center operator perceives that a call from within the elevator constitutes a medical or other emergency, Purchaser hereby gives ThyssenKrupp Elevator the express permission to call Local Emergency Services at the telephone numbers provided by the Purchaser in Section 3 below at ThyssenKrupp Elevator's sole discretion. Under those circumstances, Purchaser agrees to pay all related charges for services provided by any Local Emergency Services in response to that call. Purchaser agrees that ThyssenKrupp Elevator shall not be responsible

for ensuring an appropriate (or any) response by Local Emergency Services to that call.

None of the services described anywhere in this Agreement includes maintenance of any type or kind of the Purchaser's telephone or other communication equipment. The Purchaser retains possession and control of its telephone and other communication equipment and is responsible for ensuring uninterrupted operation of that equipment so that it is capable of placing a call to ThyssenKrupp Communication's call center.

## ThyssenKrupp Communications Contact Information - To Be Completed by Purchaser

## Section 1, Elevator Detail:

Total number of elevators in Building :

Elevator #	Elevator Telephone Number including Area Code	Elevator #	Elevator Telephone Number including Area Code

## Section 2, Purchaser Designated Contacts:

In the event of an emergency, or perceived emergency affecting the equipment covered by this Agreement, the Purchaser designates the following as its decision-making contacts:

	Contact Name	Title	Primary Telephone #	Secondary Telephone #
1				
2				
3				

## Section 3, Local Emergency Services Contact Information:

Phone # for Local Police Department: Phone # for Local Fire Department:

( ) <del>( ) -</del>

## Section 4, Purchaser's Special Instructions:

The following are special instructions provided by Purchasers with respect to the information supplied above:

## Periodic Safety Testing (Check box if included)

ThyssenKrupp Elevator will test your equipment in accordance with those periodic testing requirements as outlined in the American National Safety Code for Elevators and Escalators, ANSI A 17.1, which are in effect at the time this agreement is executed. In the event that the state, city or local governing authority in which the equipment is located has adopted different requirements, ThyssenKrupp Elevator will test your equipment in accordance with those periodic testing requirements in effect at the time this agreement is executed. You agree to pay for any costs of the inspector and/or inspection fees. Special Considerations regarding periodic safety testing are set forth below.

## Product Information

You agree to provide ThyssenKrupp Elevator with current wiring diagrams that reflect all changes, parts catalogs, and maintenance instructions for the equipment covered by this agreement (exception: we will supply all of the above for new ThyssenKrupp elevators at no additional cost). You agree to authorize us to produce single copies of any programmable device(s) used in the equipment for the purpose of archival back-up of the software embodied therein. These items will remain your property.

## **Safety**

You agree to instruct or warn passengers in the proper use of the equipment and to keep the equipment under continued surveillance by competent personnel to detect irregularities between elevator examinations. You agree to immediately report any condition that may indicate the need for correction before the next regular examination. You agree to immediately shut down the equipment upon manifestation of any irregularities in either the operation or the appearance of the equipment, to immediately notify us, and to keep the equipment shut down until the completion of any repairs. You agree to give us immediate verbal notice and written notice within ten (10) days after any occurrence or accident in or about the elevator. You agree to provide our personnel with a safe place to work. You agree to provide a suitable machine room, including secured doors, waterproofing, lighting, ventilation, and appropriate air temperature control to maintain that room at a temperature between 50°F and 90°F. You also agree to maintain the elevator pit in a dry condition at all times. Should water or other liquids become present, you will contract with others for removal and the proper handling of such liquids. We reserve the right to discontinue work in the building whenever, in our sole opinion, our personnel do not have a safe place to work. You also agree that if ThyssenKrupp Elevator's inspection of a piece of equipment serviced under this agreement reveals an operational problem which, in ThyssenKrupp Elevator's sole judgment, jeopardizes the safety of the riding public, ThyssenKrupp Elevator may shut down the equipment until such time as the operational problem is resolved. In that event, ThyssenKrupp Elevator will immediately advise you in writing of such action, the reason for such action, and whether any proposed solution is covered by the terms of this agreement.

## <u>Other</u>

You agree not to permit others to make alterations, additions, adjustments, or repairs or replace any component or part of the equipment during the term of this agreement. You agree to accept our judgment as to the means and methods employed by us for any corrective work under this agreement. Since ThyssenKrupp Elevator's top priority is the satisfaction of its customers, if you should have any concern(s) with the means and methods used to maintain or repair the equipment covered under this agreement, you agree to provide us with written notice of that concern and give us thirty (30) days to respond either in writing or commence action to appropriately resolve it.

In the event of the sale, lease or other transfer of the ownership or management of the premises in which the elevator(s) or equipment described herein are located, you agree to see that such transferee is made aware of this agreement and agrees to assume and/or be bound by the conditions hereof for the balance of the unexpired term of this agreement. Should the transferee fail to assume this agreement, you shall remain liable for all unpaid amounts, including those owed for the balance of the current unexpired term of this agreement.

ThyssenKrupp Elevator performing the convises herein specified. extent permitted by law to indomnify defend save harmless discharge and forever against ThyssonKrupp Eloyator domande cuite and procoodings brought ibeidiaries for loce, property damage (including damage to the equipment which is the subject matter ooroonal iniury or the Durcheser or overed by this agreement, or the associated areas surrounding such equipment. Your duty to indomnify the extent that the loss, property damage (including damage to the equipment which is the injury or dooth is determined to be caused by or resulting from the negligence Thucconkrupp Elevator and/or our **Elevator Maintenance Agreement** 

payment of all attorney's fees, court costs, judgments, settlements, interest and any other expenses of litigation arising. out of such claims or lawsuits...

### **Insurance**

You expressly agree to name ThyssenKrupp Elevator Corporation along with its officers, agents, affiliates and subsidiaries as additional insureds in your liability and any excess (umbrella) liability insurance policy(ies). Such insurance must insure ThyssenKrupp Elevator Corporation, along with its officers, agents, affiliates and subsidiaries for those claims and/or losses referenced in the above paragraph, and for claims and/or or losses arising from the seleengligence or responsibility of ThyssenKrupp Elevator Corporation and/or its officers, agents, affiliates and subsidiaries for selections and/or losses arising from the selection of the

### Items Not Covered

\*\* Please see special considerations, which will become apart of this contract\*\*

We do not cover cosmetic, construction, or ancillary components of the elevator system, including the finishing, repairing, or replacement of the cab enclosure, ceiling frames, panels, and/or fixtures, hoistway door panels, door frames, swing door hinges and closing devices, sills, car flooring, floor covering, lighting fixtures, ceiling light bulbs and tubes, main line power switches, breaker(s), feeders to controller, below ground or unexposed hydraulic elevator system, including but not limited to, jack cylinder, piston, PVC or other protective material; below ground or unexposed piping, alignment of elevator guide rails, smoke and fire sensors, fire service reports, all communication and entertainment devices, security systems not installed by us, batteries for emergency lighting and emergency lowering, air conditioners, heaters, ventilation fans, pit pumps and all other items as set forth and excluded in this agreement.

### Other Conditions

With the passage of time, equipment technology and designs will change. If any part or component of your equipment covered under this agreement cannot, in our sole opinion, be safely repaired and is no longer stocked and readily available from either the original equipment manufacturer or an aftermarket source, that part or component shall be considered obsolete. You will be responsible for all charges associated with replacing that obsolete part or component as well as all charges required to ensure that the remainder of the equipment is functionally compatible with that replacement part or component. In addition, we will not be required to make any changes or recommendations in the existing design or function of the unit(s) nor will we be obligated to install new attachments or parts upon the equipment as recommended or directed by insurance companies, governmental agencies or authorities, or any other third party. Moreover, we shall not be obligated to service, renew, replace and/or repair the equipment due to any one or more of the following: anyone's abuse, misuse and/or vandalism of the equipment; anyone's negligence in connection with the use or operation of the equipment; any loss of power, power fluctuations, power failure, or power surges that in any way affect the operation of the equipment; fire, smoke, explosions, water, storms, wind, lightening, acts of civil or military authorities, strikes, lockouts, other labor disputes, theft, riot, civil commotion, war, malicious mischief, acts of God, or any other reason or cause beyond our control that affects the use or operation of the equipment. You expressly agree to release and discharge us and our employees for any and all claims and/or losses (including personal injury, death and property damage, specifically including damage to the property which is the subject matter of this agreement) associated therewith or caused thereby. ThyssenKrupp Elevator shall also automatically receive an extension of time commensurate with any delay in performance caused by or related to the aforementioned and you expressly agree to release and discharge ThyssenKrupp Elevator from any and all claims for consequential, special or indirect damages arising out of the performance of this agreement. In no event shall ThyssenKrupp Elevator's liability for damages arising out of this agreement exceed the remaining unpaid installments of the current, unexpired term of this agreement

Should your system require any of the safety tests on the commencement date of this agreement, ThyssenKrupp Elevator assumes no responsibility for the day-to-day operation of the governor or safeties on traction elevators, or the hydraulic system on hydraulic elevators under the terms of this agreement until the test has been completed and the equipment passed. Should the respective system fail any of those tests, it shall be your sole responsibility to make necessary repairs and place the equipment in a condition that we deem acceptable for further coverage under the terms

of this agreement. We shall not be liable for any damage to the building structure or the elevator resulting from the performance of any safety tests we perform at any time under this agreement. If during the initial firefighter's service test, that feature is found to be inoperable, you shall be responsible for all costs associated with necessary repair(s) to bring the elevator(s) into compliance with the applicable elevator codes in your local jurisdiction.

In the event an Attorney is retained to enforce, construe or defend any of the terms and conditions of this agreement or to collect any monies due hereunder, either with or without litigation, the prevailing party shall be entitled to recover all costs and reasonable attorney's fees.

You hereby waive trial by jury. You agree that this agreement shall be construed and enforced in accordance with the laws of the state where the equipment is located. You consent to jurisdiction of the courts, both state and Federal, of the state in which the equipment is located as to all matters and disputes arising out of this agreement.

In the event any portion of this agreement is deemed invalid or unenforceable by a court of law, public policy or statute, such finding shall not affect the validity or enforceability of any other portion of this agreement.

Our rights under this agreement shall be cumulative and our failure to exercise any rights given hereunder shall not operate to forfeit or waive any of said rights and any extension, indulgence or change by us in the method, mode or manner of payment or any of its other rights shall not be construed as a waiver of any of its rights under this agreement.

## Price.

The price for the services as stated in this agreement shall be One Hundred Ninety Dollars (\$190.00) per month, excluding taxes, payable Quarterly in advance.

### <u>Term</u>

This agreement is effective for Sixty (60) month(s) starting 06/01/2018 and is non-cancelable. To ensure continuous service, this agreement will be automatically renewed for successive Sixty (60) month periods, unless either party timely serves written notice upon the other party of its intention to cancel renewal at least ninety (90) days but not more than 120 days before the end of the initial Sixty (60) month period, or at least ninety (90) days but not more than 120 days before the end of any subsequent Sixty (60) month renewal period. Notice shall be sent by certified mail, return receipt requested to the address set forth on page 1 of this agreement. Time is of the essence.

### Annual Price Adjustments

Since our costs to provide you with the service set forth in this agreement may increase, we reserve the right to adjust the price of our service under this agreement accordingly. In the event this occurs, we will adjust your monthly price based on the percentage change in the average rate paid to elevator examiners. This rate paid to elevator examiners consists of the hourly rate paid to examiners plus fringe benefits and union welfare granted in place of or in addition to the hourly rate. Fringe benefits include pensions, vacations, paid holidays, group insurance, sickness and accident insurance, and hospital insurance. We also reserve the right to make additional adjustment to the price of our service under this agreement and/or enact surcharges as needed to account for increased fuel prices when such increases exceed the Consumer Price Index (CPI) current rate. We also reserve the exclusive right to make additional adjustment to the price of our service under this agreement in the event that the equipment covered by this agreement is modified from its present state.

## Early Payment Discount

You may elect to pay in advance for twelve (12) months of service described in this agreement. Such a pre-payment entitles you to a 3% discount from the annual price in effect at the time of payment.

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## **Overdue Invoices**

A service charge of 1½% per month, or the highest legal rate, whichever is more, shall apply to all overdue accounts you have with ThyssenKrupp Elevator that are in any way related to your equipment described in this agreement. If you do not pay any sum due to ThyssenKrupp Elevator related to your equipment described in this agreement, regardless of whether it is billed pursuant to this agreement or any other with us, within sixty (60) days from the billing date, we may also choose to do one or more of the following: 1) suspend all service until all amounts due have been paid in full, and/or 2) declare all sums for the unexpired term of this agreement due immediately as liquidated damages and terminate our obligations under this agreement. If ThyssenKrupp Elevator elects to suspend service, we shall not be responsible for personal injury, death, damage to property (including damage to the equipment that is the subject matter of this agreement) or losses of any other type or kind that is in any way related the ThyssenKrupp Elevator's suspension of service. Upon resumption of service, you will be responsible for payment to ThyssenKrupp Elevator for all costs we incur that result from our suspension of service and to remedy any damage caused to your equipment during that time. Time is of the essence.

## **Special Considerations**

Annual escalations will not exceed 4%.

Additional insured coverage shall only apply to the extent any damages covered by the policy are determined to be caused by Contractor's acts, actions, omissions or neglects and not to the extent caused by the additional insured's own acts, actions, omissions or neglects or for bare allegations.

## **Acceptance**

Your acceptance of this agreement and its approval by an authorized manager of ThyssenKrupp Elevator will constitute exclusively and entirely the agreement for the services herein described. All other prior representations or agreements, whether written or verbal, will be deemed to be merged herein and no other changes in or additions to this agreement will be recognized unless made in writing and properly executed by both parties. Should your acceptance be in the form of a purchase order or other similar document, the provisions of this agreement will govern, even in the event of a conflict. This proposal is hereby accepted in its entirety and shall constitute the entire agreement as contemplated by you and us. This proposal is submitted for acceptance within one-hundred twenty (120) days from the Date Submitted by the ThyssenKrupp Elevator representative indicated below.

No agent or employee shall have the authority to waive or modify any of the terms of this agreement without the prior written approval of an authorized ThyssenKrupp Elevator manager.

ThyssenKrupp Elevator Corporation:	Dare County Detention Center:	ThyssenKrupp Elevator Corporation Approval:
By:	By: (Signature of Authorized Individual)	By: (Signature of Authorized Individual)
Jordan Marley Account Manager jordan.marley@thyssenkrupp.com	(Print or Type Name)	Greg Sutton Branch Manager
	(Print or Type Title)	
4/23/2018 (Date Submitted)	(Date of Approval)	(Date of Approval)



## WORK ORDER

Date: April 23, 2018

Purchaser:	Dare County Detention Center	Location:	Dare County Detention Center
Address:	Po Box 2179		1044 Driftwood Dr
City/State/Zip:	Manteo, NC 27954-2179		Manteo, NC 27954-9349

Purchaser authorizes thyssenkrupp Elevator Corporation (referred to as "thyssenkrupp Elevator" hereafter) to perform the following work on the equipment and at the location described above, in exchange for the sum of **Five Thousand Six Hundred Dollars (\$5,600.00)** plus any applicable tax pursuant to the terms and conditions contained in this Work Order (the "Work Order").

### Scope of Work:

### Door Edge

thyssenkrupp Elevator will furnish and install one new electronic door edge on the elevator at the above location to replace the existing mechanical safety edge. This electronic edge senses the presence of an obstruction in the door opening with a screen of infrared beams. If obstructions are detected in this area, the doors will reopen. This new electronic door edge will reduce the chance of a closing elevator door injuring passengers.

### Solid State Starter

thyssenkrupp Elevator will provide and install a solid state starter at the above referenced location. We shall remove the existing mechanical starter contactor assembly. We shall provide and install a new solid state starter to control motor starting and limit the inflow of current. The new starter shall have built-in protection for overload conditions, reverse phase, and loss of phase. The new starter shall be wired, adjusted, and tested for smooth operation.

No permits or inspections by others are included in this work, unless otherwise indicated herein. Delivery and shipping is included. All work is to be performed during regular working days and hours as defined in this Work Order unless otherwise indicated herein.

## **Terms and Conditions**

thyssenkrupp Elevator does not assume any responsibility for any part of the vertical transportation equipment other than the specific components that are described in this Work Order and then only to the extent thyssenkrupp Elevator has performed the work described above.

No work, service, examination or liability on the part of thyssenkrupp Elevator is intended, implied or included other than the work specifically described above. It is agreed that thyssenkrupp Elevator does not assume possession or control of any part of the vertical transportation equipment and that such remains Purchaser's exclusively as the owner, lessor, lessee, possessor, or manager thereof.

Unless otherwise stated herein, thyssenkrupp Elevator's performance of this Work Order is expressly contingent upon Purchaser securing permission or priority as required by all applicable governmental agencies and paying for any and all applicable permits or other similar documents.

It is agreed that thyssenkrupp Elevator's personnel shall be given a safe place in which to work. thyssenkrupp Elevator reserves the right to discontinue its work in the location above whenever, in its sole opinion, thyssenkrupp Elevator believes that any aspect of the location is in any way unsafe until such time as Purchaser has demonstrated, at its sole expense, that it has appropriately remedied the unsafe condition to thyssenkrupp Elevator's satisfaction. Unless otherwise agreed, it is understood that the work described above will be performed during regular working days and hours which are defined as Monday through Friday, 8:00 AM to 4:30 PM (except scheduled union holidays). If overtime is mutually agreed upon, an additional charge at thyssenkrupp Elevator's usual rates for such work shall be added to the price of this Work Order.

In consideration of thyssenkrupp Elevator performing the work described above Purchaser, to the fullest extent permitted by law, expressly agrees to indomnify, defend, save harmless, discharge, release and ferever acquit thyseenkrupp



## \*\* Please see bottom of page 3, which will become apart of this contract\*\*

gents, affiliates, and subsidiaries from edings made or brought against thresenkrupp Elevator ite omnlovoos -property damage (including damage -th that alloged to have d by Purchaso do installation, removal manufacturó docian ansportation equipment that is the subject of this Work Order or the associated areas rehasor's duty to indemnify does not apply to the extent that the loss, property damage (including is the subject matter of this Wark Order), personal injury or death is determined quipmont which resulting from the negligence of thyssenkrupp Elevator and/or its employees. Purchaser recognizes, however, that its bligation to defend thyssenkrupp Elevator and its employees, officers, agents, affiliates and subsidiaries under this vause is breader and distinct from its duty to indomnify and specifically includes payment of all atterney's fees, cour costs interest and any other expenses of litigation arising out of such claims or lawsuits M

Purchaser expressly agrees to name thyssenkrupp Elevator along with its officers, agents, affiliates and subsidiaries as additional insureds in Purchaser's liability and any excess (umbrella) liability insurance policy(ies). Such insurance must insure thyssenkrupp Elevator, along with its officers, agents, affiliates and subsidiaries for those claims and/or losses referenced in the above paragraph, and for claims and/or or losses arising from the negligence or legal responsibility of thyssenkrupp Elevator and/or its officers, agents, affiliates and subsidiaries. Such insurance must thyssenkrupp Elevator and/or its officers, agents, affiliates and subsidiaries. Such insurance must specify that its coverage is primary and non-contributory. Purchaser bereby waives the right of subrogation.

thyssenkrupp Elevator shall not be liable for any loss, damage or delay caused by acts of government, labor, troubles, strikes, lockouts, fire, explosions, theft, riot, civil commotion, war, malicious mischief, acts of God, or any cause beyond its control. thyssenkrupp Elevator Corporation shall automatically receive an extension of time commensurate with any delay regarding the work called for in this Work Order.

Should loss of or damage to thyssenkrupp Elevator's material, tools or work occur at the location that is the subject of this Work Order, Purchaser shall compensate thyssenkrupp Elevator therefor, unless such loss or damage results solely from thyssenkrupp Elevator's own acts or omissions.

If any drawings, illustrations or descriptive matter are furnished with this Work Order, they are approximate and are submitted only to show the general style and arrangement of equipment being offered. Work Order.

Purchaser shall bear all cost(s) for any reinspection of thyssenkrupp Elevator's work due to items outside the scope of this Work Order or for any inspection arising from the work of other trades requiring the assistance of thyssenkrupp Elevator.

Purchaser expressly agrees to waive any and all claims for consequential, special or indirect damages arising out of the performance of this Work Order and specifically releases thyssenkrupp Elevator from any and all such claims.

A service charge of 1.5% per month, or the highest legal rate, whichever is less, shall apply to delinquent accounts. In the event of any default of any of the payment provisions herein, Purchaser agrees to pay, in addition to any defaulted amount, any attorney fees, court costs and all other expenses, fees and costs incurred by thyssenkrupp Elevator in connection with the collection of that defaulted amount.

Purchaser agrees that this Work Order shall be construed and enforced in accordance with the laws of the state where the vertical transportation equipment that is the subject of this Work Order is located and consents to jurisdiction of the courts, both state and Federal, of that as to all matters and disputes arising out of this Work Order. Purchaser further agrees to waive trial by jury for all such matters and disputes.

The rights of thyssenkrupp Elevator under this Work Order shall be cumulative and the failure on the part of the thyssenkrupp Elevator to exercise any rights given hereunder shall not operate to forfeit or waive any of said rights and any extension, indulgence or change by thyssenkrupp Elevator in the method, mode or manner of payment or any of its other rights shall not be construed as a waiver of any of its rights under this Work Order.

In the event any portion of this Work Order is deemed invalid or unenforceable by a court of law, such finding shall not affect the validity or enforceability of any other portion of this Work Order.

This Work Order shall be considered as having been drafted jointly by Purchaser and thyssenkrupp Elevator and shall not be construed or interpreted against either Purchaser or thyssenkrupp Elevator by reason of either Purchaser or thyssenkrupp Elevator's role in drafting same.

In the event Purchaser's acceptance of the work called for in this Work Order is in the form of a purchase order or other kind of document, the provisions, terms and conditions of this Work Order shall exclusively govern the relationship between thyssenkrupp Elevator and Purchaser with respect to the work described herein.



# Acceptance

This Work Order is submitted for acceptance within 30 days from the date executed by thyssenkrupp Elevator. Unless otherwise stated, the Purchaser agrees to pay as follows: 50% upon signed acceptance of this Work Order and \$2,800.00 upon completion of the work described in this Work Order.

Purchaser's acceptance of this Work Order will constitute exclusively and entirely the agreement for the work herein described. All prior representations or agreements regarding this work, whether written or verbal, will be deemed to be merged herein, and no other changes in or additions to this Work Order will be recognized unless made in writing and properly executed by both parties. No agent or employee of thyssenkrupp Elevator shall have the authority to waive or modify any of the terms of this Work Order without the written approval of an authorized thyssenkrupp Elevator manager. This Work Order specifically contemplates work outside the scope of any other contract currently in effect between the parties; any such contract shall be unaffected by this Work Order.

To indicate acceptance of this work order, please sign and return one (1) original of this agreement to the address shown below. Upon receipt of your written authorization and required materials and/or supplies, we shall implement the work called for in this Work Order.

	thyssenkrupp Elevator Corporation:	Dare C	County Detention Center (PURCHASER):
By:	Jordon G. Marley	By:	
-	(Signature of thyssenkrupp Elevator Representative)		(Signature of Authorized Individual)
	Jordan Marley Account Manager jordan.marley@thyssenkrupp.com		Charles Henderson
	+1 757 6927214		(Print or Type Name)
			(Print or Type Title)
	04-23-2018		
-	(Date of Submission)		(Date of Acceptance)
	thyssenkrupp Elevator Cor	poration	Approval
	(Date of Approval) (S	Signature	e of Branch Representative)
			Greg Sutton Branch Manager

Additional insured coverage shall only apply to the extent any damages covered by the policy are determined to be caused by Contractor's acts, actions, omissions or neglects and not to the extent caused by the additional insured's own acts, actions, omissions or neglects or for bare allegations.



# SCHEDULING AND PRODUCTION REQUEST FOR PAYMENT

Please Remit To:

thyssenkrupp Elevator Corporation PO Box 933004 Atlanta, GA 31193-3004

Attn: Charles Henderson Dare County Detention Center Po Box 2179 Manteo NC, 27954-2179

Date	Terms	Reference ID	Customer Reference # / PO
April 23, 2018	Immediate	ACIA-1EBKVL9	

Total Contract Price:		\$5,600.00
Down Payment:	(50%)	\$2,800.00
Amount Due upon Acceptance:		\$2,800.00

For inquiries regarding your contract or services provided by thyssenkrupp Elevator, please contact your local account manager at +1 757 6927214. To make a payment by phone, please call 908-603-4408 with the reference information provided below.

Thank you for choosing thyssenkrupp Elevator. We appreciate your business.

#### Please detach the below section and provide along with payment.

Customer Name: Location Name: Customer Number:	Dare County Detention Center Dare County Detention Center 130785		<b>Remit To:</b> thyssenkrupp Elevator Corporation PO Box 933004 Atlanta GA 31193-3004
Reference ID:	ACIA-1EBKVL9	]	
Remittance Amount:	\$2,800.00	]	



**Board Appointments** 

### Description

The Dare County Board of Commissioners will consider the following Board Appointments:

Extra Territorial Jurisdiction District - Nags Head Zoning Board of Adjustment - Dare County

Complete information about the appointments appear after this page.

Upcoming Board Appointments for the next three months are listed at the end.

#### **Board Action Requested**

Make Board Appointments and Announce Upcoming Appointments

### **Item Presenter**

Robert Outten, County Manager

# **Board Appointments – May 7, 2018**

# Extra Territorial Jurisdiction District – Nags Head

• Peregrine White's term expires and he would like to be reappointed.

### Zoning Board of Adjustment - Dare

- Jay Hart's term expires and he would like to be reappointed.
- The County Code provides that the Chairman of the Zoning Board be appointed by the Dare County Board of Commissioners. Jay Hart was appointed Chairman at the November 6, 2017 Board of Commissioners Meeting.
- Mr. Hart would like to remain Chairman
- Applications have been received from Allen Moran, William Simmonds, Stephen Smith, Amanda Hooper Walters

# **UPCOMING BOARD APPOINTMENTS**

June 2018	Dare County Waterways
	Fessenden Center Advisory Board
	Hatteras Community Center
	Juvenile Crime Prevention Council
	Library Board – Dare
	Manns Harbor Community Center
	Roanoke Island Community Center
	Rodanthe, Waves, Salvo Community Center
	Town of Southern Shores Zoning Board of Adjustment
	Transportation Advisory Board
July 2018	Airport Authority
and a set of the set o	East Lake Community Center Board
	Game and Wildlife Commission
	Library Board – Regional
	Parks and Recreation Advisory Council
	Wanchese Community Center Board
August 2018	ABC Board
August Loro	Airport Authority
	Dare County Center Advisory Board



Extra Territorial Jurisdiction (ETJ) District (Town of Nags Head)

# Description

See attached summary

# **Board Action Requested**

Take Appropriate Action

# **Item Presenter**

Robert Outten, County Manager

#### **BOARD APPOINTMENT**

### EXTRA TERRITORIAL JURISDICTION (ETJ) DISTRICT

(Three Year Term) (Town of Nags Head)

The following term expires this month:

# **Peregrine White**

(Appointed 6/15)

Mr. White would like to be reappointed.

An application has been received from: Allen Moran

1

The Dare County Board of Commissioners believes all citizens should have the opportunity to participate in governmental decisions. One way of participating is by serving as a citizen member on one of the county's advisory boards or committees. If you would like to be considered for appointment to an advisory board or committee, please complete the form below and mail to Rhonda Creef, Dare County Deputy Clerk to the Board, P.O. Box 1000, Manteo, N.C. 27954 or fax it to her at 473-6312, or send it by email to rhonda@darenc.com

Advisory Board or Committee interested in:
1 <sup>st</sup> choice Extra Territorial Juristdiction (ETJ) District- Nags Head
2 <sup>nd</sup> choice
3 <sup>rd</sup> choice
Name Allen Moran
Address 381 Mother Vineyard Rd
City/State/Zip Manteo, NC 27954
Email Address allenm@darenc.com
Telephone Home: 252-423-1309
Business: 252-475-9222
Resident of Dare County:yesno
Occupation: Jail Administrator, Dare County / Real Estate Agent
Business Address: 1044 Driftwood Dr Manteo, NC 27954
Educational background:
Business and civic experience and skills:

Other Boards/Committees/Commissions on which you presently serve:

# REFERENCES

\_\_\_\_\_

List three persons who are not related to you and who have definite knowledge of your qualifications for the position for which you are applying.

Name	<b>Business/Occupation</b>	Address	Telephone
	· · · · · · · · · · · · · · · · · · ·		
hereby au	nd this application will be kept on t thorize Dare County to verify all in	formation included in	this application.
Date: _0	<u>5/19/15</u> Signature of ap	plicant: <u>(      -</u>	///

FOR OFFICE USE ONLY:

A STREET, STREE

Date received:

# EXTRA TERRITORIAL JURISDICTION (ETJ) DISTRICT

(Three Year Term) (Town of Nags Head)

#### MEMBER ,

#### TERM EXPIRATION

#### ACTION

Peregrine White

#### 5-2018

Apptd. 6/15

423 W. Villa Dunes Dr. Nags Head, NC 27959 441-7062 (H) 256-2421 (O)

NOTE: Dare County appointee serves as a member of the Nags Head Planning Board as well as a member of the nags Head Board of Adjustment and represents Dare County in the ETJ District.

Peregrine White replaced Moncie "Punk" Daniels 6/15.

#### **REVISED 6/15**



Zoning Board of Adjustment - Dare

# Description

See attached

# **Board Action Requested**

Take Appropriate Action

# **Item Presenter**

Robert Outten, County Manager

May, 2018

#### **BOARD APPOINTMENTS**

#### DARE COUNTY BOARD OF ADJUSTMENT

(Three Year Term)

The following term expires this month:

Jay Hart

(Current Term 5/15 – 5/18) (Originally Apptd. 4/05)

The County Code provides that the Chairman of the Zoning Board be appointed by the Dare County Board of Commissioners. Jay Hart was appointed Chairman at the November 6, 2017 Board of Commissioners Meeting.

> Jay Hart would like to be reappointed. Mr. Hart would also like to remain Chairman.

Applications have been received from:

Allen Moran William Simmonds Stephen Smith Amanda Hooper Walters

Other Members: See attached list

The Dare County Board of Commissioners believes all citizens should have the opportunity to participate in governmental decisions. One way of participating is by serving as a citizen member on one of the county's advisory boards or committees. If you would like to be considered for appointment to an advisory board or committee, please complete the form below and mail to Janice Williams, P.O. Box 1000, Manteo, N.C. 27954 or fax it to her at 473-1817, or send it by email to janicew@darenc.com

Advisory Board or Committee interested in:

1st choice <u>Planning Board</u> 4) Board of Adjustment
2nd choice ABC Board 5.) Equalization 3 Review
3rd choice Tourism Board 6) Health & Human Services
Name Allen Moran
Address 381 Mother Vineyard Rd
City/State/Zip Manteo NC 27954
Email Address <u>allenm@darenc.com</u>
Telephone Home: (252) 423 - 1309
Business: (252) 475-9222
Resident of Dare County: ves no
Occupation: Police Officer / Real Estate Broker / Restaurateur
Business Address: 7623 S. Virginia Dare Trl Nags Head NC
Educational background:
NC licensed real estate broker, NC Justice Academy,
College of the Albemorle
Business and civic experience and skills:
Rotory International Community Service Chair (Mantco, 2012),
U.S. Restaurant Association Board Member

Other Boards/Committees/Commissions on which you presently serve:

NCDOT Board, Roanoke Island Community Center,
Albemarle Regional Planning Organization,
Peanut Belt Regional Planning Organization
REFERENCES

List three persons who are not related to you and who have definite knowledge of your qualifications for the position for which you are applying.

Name	Busines	s/Occupation	Address	Telephone
RV Ü	wens Self-	Employed	Manteo, NC	216-8079
Dova		Sheriff (Dare)	KOH NC	216-9898
Marc		Retired	Manteo NC	216.6703
			1	

I understand this application will be kept on the active file for three years and I hereby authorize Dare County to verify all information included in this application.

Date: 02/02/2018 Signature of applicant: ale m

FOR OFFICE USE ONLY:

Date received: \_\_\_\_\_

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The Dare County Board of Commissioners believes all citizens should have the opportunity to participate in governmental decisions. One way of participating is by serving as a citizen member on one of the county's advisory boards or committees. If you would like to be considered for appointment to an advisory board or committee, please complete the form below and mail to Janice Williams, P.O. Box 1000, Manteo, N.C. 27954 or fax it to her at 473-1817, or send it by email to janicew@darenc.com

1 <sup>st choice</sup> Dare County Waterways Commission
2 <sup>nd</sup> choice Dare County Board of Adjustment
3 <sup>rd</sup> choice ABC Board
Name William Simmonds
Address 147 W. Oak Knoll Dr
City/State/Zip Nags Head, NC 27959
Email Address wsimm1017@gmail.com
Telephone Home: 321-607-4241
Business:
Resident of Dare County: X yes no
Occupation: Recently retired NASA, Kennedy Space Center, Florida
Business Address:
Educational background:
BS Mechanical Engineering, Old Dominion University, Masters Engineering Management, George Washington University

Advisory Board or Committee interested in:

Business and civic experience and skills:

Solid Waste Advisory Board - Hampton, Virginia, 1989-1992, Project Manager, (PM) KSC Railroad Bridge upgrades,

PM, Indian River Dredging Project, KSC, NASA & AF Barge and Wharf Terminal Improvement Project, Brevard County, Florida, Youth Science Fair Judge.

Other Boards/Committees/Commissions on which you presently serve:

a j

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# REFERENCES

2

List three persons who are not related to you and who have definite knowledge of your qualifications for the position for which you are applying.

Name	<b>Business/Occupation</b>	Address	I elepnone
Steve Milton,	, PM Chief, NASA Mail Code LX-D1 Johr	n F. Kennedy Space Center	; FL 32899 (321) 867-5965
Eric Andersor	n, Launch & Ops Div. Chief, Mail Code VAE0	0 John F. Kennedy Space Cer	nter, FL 32899 (321) 867-5000
Ross A. Kea	rney, retired, former Mayor Hampton of C	ity, 328 Darby Ave. Hampto	n, Va. 23663 (757)-268-4081
hereby aut	nd this application will be kept on thorize Dare County to verify all ir 8/03/2017 Signature of a	the active file for three nformation included in oplicant:	this application.
FOR OFFI	ICE USE ONLY:		
Date recei	ved:		

The Dare County Board of Commissioners believes all citizens should have the opportunity to participate in governmental decisions. One way of participating is by serving as a citizen member on one of the county's advisory boards or committees. If you would like to be considered for appointment to an advisory board or committee, please complete the form below and mail to Rhonda Creef, Dare County Deputy Clerk to the Board, P.O. Box 1000, Manteo, N.C. 27954 or fax it to her at 473-6312, or send it by email to rhonda@darenc.com

Advisory Board or Committee interested in:
1st choice ABC Board
2nd choice Planning Board - At Large, Dist. 2
3rd choice Zoning Board of Adjustments
Name Stephen Smith
Address 321 Jean Ct.
City/State/Zip Kill Devil Hills, NC 27948
Email Address target 198 2002 @ yahoo. com
Telephone Home: (252) 216-6820
Business: (252) 475 - 5980
Resident of Dare County: ves no
Occupation: Deputy Sheriff
Business Address: 962 Marshall C. Collins Dr.
Educational background:
B.A. Criminal Justice - UNC - Wilmington
M.P.A - Planning Concentration - ECU
Business and civic experience and skills:
12 years haw enbroument, 4 years W/ North Carolina Emergency Mgt,
4 years Planning/Code w/Town of Kitty Hawk

310

Other Boards/Committees/Commissions on which you presently serve:

lone

#### REFERENCES

List three persons who are not related to you and who have definite knowledge of your qualifications for the position for which you are applying.

Name	Busir	ness/Occupation	Address	Telephone
Beverly	Boswell	Medical/DCBOC	KDH	(252)216-9820
Doug	Doughtic	'Deso	KD14	(252) 216-9898
Jordan	Hennessy	Aide to Sen, Cook	Southern Shores	(252) 619-3606
			45 85 85	20 A

I understand this application will be kept on the active file for three years and I hereby authorize Dare County to verify all information included in this application.

FOR OFFICE USE ONLY:

Date received:

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The Dare County Board of Commissioners believes all citizens should have the opportunity to participate in governmental decisions. One way of participating is by serving as a citizen member on one of the county's advisory boards or committees. If you would like to be considered for appointment to an advisory board or committee, please complete the form below and mail to Janice Williams, P.O. Box 1000, Manteo, N.C. 27954 or fax it to her at 473-1817, or send it by email to janicew@darenc.com

Advisory Board or Committee interested in:

1 <sup>st choice</sup> Parks and Recreation					
2 <sup>nd</sup> choice Northeastern Workforce Development					
3 <sup>rd</sup> choice Zoning Board of Adjustments					
Name Amanda Hooper Walters					
Address 1202 9th Ave					
City/State/Zip Kill Devil Hills, NC 27948					
Email Address manda.hooper@icloud.com					
Telephone Home: 252-202-9923					
Business: 252-202-9923					
Resident of Dare County: X yes no					
Occupation: Property Manager					
Business Address: 1202 9th Ave. KDH, NC 27948					
Educational background:					
Bachelor of Science, Business Admin, ECU					
Assosicate of Arts, College of the Albemarle					
Business and civic experience and skills:					

Outer Banks Mommy and Me, Board Member 2009-2011: OBX Aquatics Board

Member, 2014-2016: Outer Banks Local Food Council 2013-2016

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Other Boards/Committees/Commissions on which you presently serve: n/a

#### REFERENCES

List three persons who are not related to you and who have definite knowledge of your qualifications for the position for which you are applying.

Name	Business/Occupation	Address	Telephone
Karen Brown	Chamber of Commerce	252-44	41-8144
Bob Peele	Wachese Industrial Par	k 252-47	73-5867
Sandy Semans	133 Bayview Dr. Stumpy P	oint, 252-305	5-7284

I understand this application will be kept on the active file for three years and I hereby authorize Dare County to verify all information included in this application.

Date: 2/3/2018 Signature of applicant:

FOR OFFICE USE ONLY: 18 Date received: \_ 2

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#### DARE COUNTY BOARD OF ADJUSTMENT

(Initial Staggered Term/Three Year Term)

The Board of Adjustment meets to hear variances and appeals related to land use issues in the unincorporated areas of Dare County. The Chair is appointed by the Board of Commissioners and the Planning Department serves as administrative staff for this Board.

MEMBER	TERM EXPIRATION	ACTION
<mark>Jay Hart, Chairman</mark> P.O. Box 1782 Kill Devil Hills, NC 27948 207-7900 Colington Area	<mark>5-30-18</mark>	Apptd. 4-05 Reapptd. 5/06,09,12,15
Edward Mann, Jr. 415 Highway 64 Manteo, NC 27954 423-1215 eddiemann86@gmail.com Roanoke Island	5-30-20	Apptd. 5/17
Thomas Murphy P.O. Box 147 Rodanthe, NC 27968 987-2656 Hatteras Island	5-30-19	Apptd. 6-03 Reapptd. 5-04,07,10,13, 16
Shelly R. Jones 5013 Martins Point Road Kitty Hawk, NC 27949 261-8878 shellyjones@gmail.com Martins Point Area	5-30-19	Apptd. 10/17
Anna Creef 5297 Mashoes Rd. Manns Harbor, NC 27953 473-3339 Dare Mainland	5-30-20	Apptd. 6-03 Reapptd.5-05,08,11,14, 17

#### **ALTERNATES**

Vacant Vacant

#### NOTES:

CONTACT INFO: Donna Creef, Planning Director

MEETING DATE: No Set Date

Jay Hart filled unexpired term of Jacob Maestas 4/05. Andrew Keeney replaced David Overton (alternate) 4/05. Patricia Austin apptd. to fill unexpired term of Michael Egan 5/06. Roland Bowser replaced Patricia Austin 5/08 Edward Mann, Jr replaced Roland Bowser 5/17 Shelly Jones filled unexpired term of David Jones who resigned 10/17. Jay Hart appointed Chairman 11/17

REVISED 11/17



Upcoming Board Appointments

#### Description

The Dare County Board of Commissioners welcomes citizen participation on its many Boards and Committees.

Following is a list of the Boards and Committees that have terms expiring during the next 3 months. The list indicates when the item will be presented to the County Commissioners and any requirements that may pertain to the appointment.

Instructions on how to obtain and submit an application are attached along with additional information about each of the Boards and Committees with upcoming term appointments.

#### **Board Action Requested**

None

#### **Item Presenter**

Robert Outten, County Manager

#### Upcoming Board & Committee Appointments

The Dare County Board of Commissioners welcomes citizen participation on Advisory Boards and Committees. This type of grassroots public involvement is the foundation of democracy and a vital part of maintaining Dare County as a quality place to live.

Following is a list of Boards and Committees that have terms expiring during the next 3 months. The list highlights when the item will be presented to the Board of Commissioners along with any special requirements that may pertain to the appointment.

Information about how to obtain and submit applications follows the list.

#### June 2018

#### 1. Dare County Waterways

This Commission promotes the Oregon Inlet Jetty Project, the Hatteras Inlet Project and oversees County dredging projects and waterways related issues. 4 terms expiring

#### 2. Fessenden Center Advisory Board

This Advisory Board establishes goals and policies to enhance the Fessenden Center operation and community outreach consistent with the goals, objectives, and policies of Dare County. The overall objective is to develop procedures and operations that improve the quality of life through interaction of all age groups on Hatteras Island. 6 terms expiring

## 3. <u>Hatteras Community Center</u> This board operates and maintains the Hatteras Community Center. 2 terms expiring

#### 4. Juvenile Crime Prevention Council

As outlined and funded by the Juvenile Justice Reform Act of 1998, the Juvenile Crime Prevention Council assumes responsibility for assessing needs, funding community-based alternatives for troubled youth who enter the courts, and supporting prevention programs. 6 terms expiring

#### 5. Library Board – Dare

This Board establishes local policies within those set by the Regional Library Board and oversees the Library Trust Fund Budget; and also serves on the Board of the Dare County Library Foundation, a 503-C3 tax-exempt organization. 3 terms expiring

#### 6. Manns Harbor Community Center

This Board operates and maintains the community center facility and amenities for the use and benefit of Manns Harbor residents. 2 terms expiring

#### 7. Roanoke Island Community Center

This Board operates and maintains the community center facility and amenities for the use and benefit of all members of the community. 3 terms expiring

8. Rodanthe, Waves, Salvo Community Center

This Board operates and maintains the Rodanthe, Waves, Salvo community center facility and amenities for the use and benefit of all members of the villages. 2 terms expiring

 <u>Town of Southern Shores Zoning Board of Adjustment</u>
 This Board includes all Town of Southern Shores Planning Board Members and a Dare County Representative. 1 term expiring

#### 10. Transportation Advisory Board

The Dare County Transportation System is required by the State's Community Transportation Program to have a local Transportation Advisory Board. This Board is expected to maintain a minimum level of coordinated transportation service and to maintain ongoing communications as a means of seeking public involvement and ongoing administrative oversight. 5 terms expiring

#### July 2018

#### 1. Airport Authority

The mission of the Dare County Airport Authority is to manage the operation, maintenance and improvement of air services and facilities for the use, convenience, and benefit of the air traveling public. 3 terms expiring

2. <u>East Lake Community Center Board</u> This Board operates and maintains the East Lake Community Center. 1 term expiring

#### 3. Game and Wildlife Commission

The Game and Wildlife Commission issues and renews duck blind licenses in all Dare County waters. Renewals and new licenses are received on a yearly basis from August through December of each year. 4 terms expiring

#### 4. Library Board – Regional

This Board serves as the governing board and sets policy for the eight libraries within the East Albemarle Regional Library System. The Board is responsible for setting region-wide policies, and approving and reviewing the regional budget. Regional library board members must be a member of the local library advisory board at the time of their appointment. 1 term expiring

#### 5. Parks and Recreation Advisory Council

This Advisory Council reviews and advises Parks and Recreation in its efforts to promote, organize, plan and coordinate activities and programs for youth and adults in Dare County. 9 terms expiring

 <u>Wanchese Community Center Board</u>
 Wanchese Community Center manages and is responsible for the upkeep of the Community Building. 2 terms expiring

#### August 2018

1. ABC Board

The Dare County Alcoholic Beverage Control (ABC) Board manages the sale of distilled spirits by Promoting excellence in customer service, fiscal responsibility, operational effectiveness, and compliance with laws that govern the sale and use of alcoholic beverages in Dare County. 3 terms expiring.

#### 2. Airport Authority

The mission of the Dare County Airport Authority is to manage the operation, maintenance and improvement of air services and facilities for the use, convenience and benefit of the air traveling public. 1 term expiring.

#### 3. Dare County Center Advisory Board

The Advisory Board works to advise and promote goals and policies to enhance the Dare County Center's operations and community outreach. 4 terms expiring

-----Instructions for Obtaining and Submitting Applications------

An application must be submitted in order for your name to be considered for a Board or Committee appointment. The form is available on the Dare County website, or by calling Janice Williams at 475-5800.

# **COMMISSIONERS' BUSINESS**

# MANAGER'S / ATTORNEY'S BUSINESS