**TEVA/RHODE ISLAND STATEWIDE OPIOID SETTLEMENT AGREEMENT**

## I. Overview

Whereas, this Agreement sets forth the terms and conditions of a Rhode Island Statewide Opioid Settlement to be implemented by entry of a Consent Judgment (hereinafter, "Consent Judgment") between and among the State of Rhode Island (defined herein), and Rhode Island Participating Subdivisions (defined herein), Teva (defined herein) (all parties collectively, "the Parties") to resolve opioid-related Claims against Teva;

Whereas, Teva has agreed to the below terms for the sole purpose of settlement, and nothing herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Teva expressly denies. No part of this Agreement, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Teva. Unless the contrary is expressly stated, this Agreement is not intended for use by any third party for any purpose, including submission to any court for any purpose other than Court approvals associated with this Agreement;

Whereas, this Agreement and the associated Consent Judgment resolve the litigation as to Teva in *State of Rhode Island v. Purdue Pharma L.P. et al.,* C.A. No. PC-2018-4555;

The terms and conditions of this Agreement are set forth herein and below:

## II. Definitions

A. "*Action*" means *State of Rhode Island v. Purdue Pharma L.P. et al.*, C.A. No. PC-2018-4555.

B. "*Agreement*" means this Settlement Agreement together with the exhibits thereto.

C. "*Bar*" means either (1) a ruling by the highest court of the State setting forth the general principle that no Subdivisions in the State may maintain Released Claims against Released Entities, whether on the ground of the Agreement (or the release in it) or otherwise; (2) a law barring Subdivisions in the State from maintaining or asserting Released Claims against Released Entities (either through a direct bar or through a grant of authority to release claims and that authority is exercised in full); or (3) a Settlement Class Resolution in the State with full force and effect. For the avoidance of doubt, a law or ruling that is conditioned or predicated upon payment by a Released Entity (apart from payment of the Settlement Amount) shall not constitute a Bar. A Bar shall constitute 100% Subdivision participation.

D. "*Case-Specific Resolution*" means either (1) a law in the State of Rhode Island barring specified Subdivisions from maintaining Released Claims against Released Entities (either through a direct bar or through a grant of authority to release claims and that authority is exercised in full); (2) a ruling by a court of

competent jurisdiction over a particular Subdivision that has the legal effect of barring the Subdivision from maintaining any Released Claims at issue against Released Entities, whether on the ground of the Agreement (or the release in it) or otherwise. For the avoidance of doubt, a law, ruling, or release that is conditioned or predicated upon a post-Effective Date payment by a Released Entity (apart from the settlement payments under this Agreement) shall not constitute a Case-Specific Resolution.

E. "*Claim*" means any past, present, or future cause of action, claim for relief, cross-claim or counterclaim, theory of liability, demand, derivative claim, request, assessment, charge, covenant, damage, debt, lien, loss, penalty, judgment, right, obligation, dispute, suit, contract, controversy, agreement, *parens patriae* claim, promise, performance, warranty, omission, or grievance of any nature whatsoever, whether legal, equitable, statutory, regulatory or administrative, whether arising under federal, state, or local common law, statute, regulation, guidance, ordinance or principles of equity, whether filed or unfiled, whether asserted or unasserted, whether known or unknown, whether accrued or unaccrued, whether foreseen, unforeseen, or unforeseeable, whether discovered or undiscovered, whether suspected or unsuspected, whether fixed or contingent, and whether existing or hereafter arising, in all such cases, including but not limited to any request for declaratory, injunctive, or equitable relief, compensatory, punitive, or statutory damages, absolute liability, strict liability, restitution, subrogation, contribution, indemnity, apportionment, disgorgement, reimbursement, attorney fees, expert fees, consultant fees, fines, penalties, expenses, costs, or any other legal, equitable, civil, administrative, or regulatory remedy whatsoever.

F. "*Claim-Over*" means a Claim asserted by any entity that is not a Releasor against a Releasee on the basis of contribution, indemnity, or other claim-over on any theory relating to Claims arising out of or related to Covered Conduct.

G. "*Covered Conduct*" means any actual or alleged act, failure to act, negligence, statement, error, omission, breach of any duty, conduct, event, transaction, agreement, misstatement, misleading statement, or other activity of any kind whatsoever from the beginning of time through the date of execution of this Agreement (and any past, present, or future consequence of any such act, failure to act, negligence, statement, error, omission, breach of duty, conduct, event, transaction, agreement, misstatement, misleading statement or other activity) arising from or relating in any way to (a) the availability, discovery, development, manufacture, packaging, repackaging, marketing, promotion, advertising, labeling, recall, withdrawal, distribution, delivery, monitoring, reporting, supply, sale, prescribing, dispensing, physical security, warehousing, use or abuse of, or operating procedures relating to, any Product, or any system, plan, policy, or advocacy relating to any Product or class of Products, including but not limited to any unbranded promotion, marketing, programs, or campaigns relating to any

Product or class of Products; (b) the characteristics, properties, risks, or benefits of any Product; (c) the reporting, disclosure, non-reporting, or non-disclosure to federal, state, or other regulators of orders for any Product placed with any Released Entity; (d) the selective breeding, harvesting, extracting, purifying, exporting, importing, applying for quota for, procuring quota for, handling, promoting, manufacturing, processing, packaging, supplying, distributing, converting, or selling of, or otherwise engaging in any activity relating to, precursor or component Products, including but not limited to natural, synthetic, semi-synthetic, or chemical raw materials, starting materials, finished active pharmaceutical ingredients, drug substances, or any related intermediate Products; or (e) diversion control programs or suspicious order monitoring related to any Product.

H. "*Consent Judgment*" means a consent decree, order, judgment, or similar action (without any admission or finding of liability) as established through this Agreement.

I. "*Court*" means the Superior Court of Providence County.

J. "*Effective Date*" means the date of entry of a final Consent Judgment.

K. "*Force Majeure Event*" means any event reasonably beyond the control of the Parties, including wars, hostilities, revolution, riots, civil commotion, national emergency, unavailability of supplies, epidemics, fire, flood, earthquake, force of nature, explosion, terrorist act, embargo, or any act of God, or any law, proclamation, regulation, ordinance, or other act or order of any court or governmental authority.

L. "*Litigating Subdivision*" means a Subdivision (or Subdivision official asserting the right of or for the Subdivision to recover for alleged harms to the Subdivision and/or the people thereof) that brought any Released Claims against any Released Entities on or before March 15, 2022. Exhibit B lists all Subdivisions in the State and includes the Litigating Subdivisions identified by the Parties as of the Execution Date.

M. "*Non-Participating Subdivision*" means a Subdivision that is not a Participating Subdivision.

N. *"Opioid Remediation"* means care, treatment, and other programs and expenditures (including, reimbursement for past programs or expenditures) designed to (1) address the misuse and abuse of opioid products; (2) treat or mitigate opioid use or related disorders; or (3) mitigate other alleged effects of, including on those injured as a result of, the opioid epidemic. Exhibit C provides a non-exhaustive list of expenditures that quality as being paid for Opioid

Remediation. Qualifying expenditures may include reasonable related administrative expenses.

O. "*Participating Subdivision*" means a Subdivision that signs the Subdivision Settlement Participation Form annexed as Exhibit D and meets the requirements for becoming a Participating Subdivision under subsection VI.A.

P. "*Participating Subdivision Population*" means the sum of the population of all Participating Subdivisions.

Q. "*Product*" means any chemical substance, whether used for medicinal or non-medicinal purposes, and whether natural, synthetic, or semi-synthetic, or any finished pharmaceutical product made from or with such substance, that is an opioid or opiate, as well as any product containing any such substance. It also includes: 1) the following when used in combination with opioids or opiates: benzodiazepine, carisoprodol, zolpidem, or gabapentin; and 2) a combination or "cocktail" of any stimulant or other chemical substance prescribed, sold, bought, or dispensed to be used together that includes opioids or opiates. For the avoidance of doubt, "*Product*" does not include benzodiazepine, carisoprodol, zolpidem, or gabapentin when not used in combination with opioids or opiates. "*Product*" includes but is not limited to any substance consisting of or containing buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, naloxone, naltrexone, oxycodone, oxymorphone, pentazocine, propoxyphene, tapentadol, tramadol, opium, heroin, carfentanil, any variant of these substances, or any similar substance. "*Product*" also includes any natural, synthetic, semi-synthetic or chemical raw materials, starting materials, finished active pharmaceutical ingredients, drug substances, and any related intermediate products used or created in the manufacturing process for any of the substances described in the preceding sentence.

R. "*Released Claims*" means any and all Claims that directly or indirectly are based on, arise out of, or in any way relate to or concern the Covered Conduct occurring prior to the Effective Date. "*Released Claims*" include any Claims that have been asserted against the Released Entities by the State or any of its Litigating Subdivisions in any federal, state, or local action or proceeding (whether judicial, arbitral, or administrative) based on, arising out of, or relating to, in whole or in part, the Covered Conduct, or any such Claims that could be or could have been asserted now or in the future in those actions or in any comparable action or proceeding brought by the State, any of its Subdivisions, or any Releasor (whether or not such State, Subdivision, or Releasor has brought such action or proceeding). Released Claims also include all Claims asserted in any proceeding to be dismissed pursuant to the Agreement, whether or not such claims relate to Covered Conduct. The Parties intend that "*Released Claims*" be interpreted broadly. This Agreement does not release Claims by private individuals. It is the

intent of the Parties that such Claims by private individuals be treated in accordance with applicable law. This Agreement also does not release any Claims that the State has or may have against Released Entities outside of Covered Conduct including claims based on state or federal antitrust violations. Released Claims is also used herein to describe Claims brought by a non-party Subdivision that would have been Released Claims if they had been brought by a Releasor against a Released Entity.

S. "*Released Entities*" means: (i) Teva; (ii) all of its respective past and present direct or indirect parents, subsidiaries, divisions, affiliates, joint ventures[1] (but excluding joint venture partners), predecessors, successors, assigns and insurers (in their capacity as such); and (iii) the past and present officers, directors, members, shareholders (solely in their capacity as shareholders of the foregoing entities), partners, trustees, employees, agents, attorneys and insurers of each of the foregoing entities and persons referenced in clauses (i) through (iii) above for actions or omissions that occurred during and related to their work for, or employment with, any of the foregoing entities with respect to the Released Claims. Released entities specifically includes, but is not limited to, named defendants Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) and also includes Anda, Inc. and each of its current and former corporate parents, direct and indirect subsidiaries, predecessors, successors, affiliates, agents and current and former employees, officers and directors and any current or former related companies.

T. "*Releasors*" means, with respect to Released Claims: (1) the State of Rhode Island; (2) each Participating Subdivision; and (3) without limitation and to the maximum extent of the power of the State of Rhode Island's Attorney General and/or each Participating Subdivision to release Claims, (a) the State of Rhode Island's and Participating Subdivisions' departments, agencies, divisions, boards, commissions, Subdivisions, districts, instrumentalities of any kind and attorneys, including its Attorney General, and any person in his or her official capacity whether elected or appointed to serve any of the foregoing and any agency, person, or other entity claiming by or through any of the foregoing, (b) any public entities, public instrumentalities, public educational institutions, unincorporated districts, fire districts, irrigation districts and other Special Districts in the State of Rhode Island, and (c) any person or entity acting in a *parens patriae*, sovereign, quasisovereign, private attorney general, qui tam, taxpayer, or other capacity

[1] The joint ventures are: PGT Healthcare (a joint venture between Teva and The Procter & Gamble Company), a joint venture between Teva and Lonza, a joint venture between Teva and Handok, and Teva Takeda Yakuhim Ltd.

seeking relief on behalf of or generally applicable to the general public with respect to the State of Rhode Island or its Subdivisions, whether or not any of them participate in this Agreement. The inclusion of a specific reference to a type of entity in this definition shall not be construed as meaning that the entity is not a Subdivision. A Participating Subdivision shall provide the Subdivision Settlement Participation Form, providing for a release to the fullest extent of the Participating Subdivision's authority.

U. "*Rhode Island Abatement Funds*" means the remediation and restitution funds paid by Teva to Rhode Island pursuant to Section III.B.1.

V. "*Rhode Island Memorandum of Understanding*" means the Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds that, among other things, allocates payments received under various opioid-related settlement agreements between the State of Rhode Island and its Participating Subdivisions and limits the use of such funds to Opioid Remediation. Exhibit E is the executed Rhode Island Memorandum of Understanding and it is the intent of the State of Rhode Island to amend the Rhode Island Memorandum of Understanding to allocate payments received under this Agreement and limit the use of such funds to Opioid Remediation as reflected in Exhibit F.

W. "*Rhode Island Qualified Settlement Fund*" means the fund into which the Annual Payments are made under Section III. The Rhode Island Qualified Settlement Fund shall be structured and operated in a manner so that it qualifies as a "Qualified Settlement Fund" within the meaning of section 468B of the Internal Revenue Code of 1986, as amended, as described in Treasury Regulations Section 1.468B-1 et seq., and shall remain subject to the continuing jurisdiction of the Court.

X. "*Settlement Amount*" means $21,000,000, which is the amount to be paid pursuant to this Agreement by or on behalf of Teva as specified in Section III.B.1 below. Except as provided in Section VII.B.1, Section VII.B.2, and Section X.D below, Teva shall not be called upon to make any payments pursuant to this Agreement in addition to the amount set forth in Section III.B.1 below. Teva shall have no responsibility for any allocation of the Settlement Amount as set forth in this Agreement.

Y. "*Settlement Product*" means "Naloxone Hydrochloride Nasal Spray" (4 mg strength), "Buprenorphine and Naloxone Sublingual Tablets CIII" (8 mg/2 mg strength), and "Buprenorphine and Naloxone Sublingual Tablets CIII" (2 mg/0.5 mg) that are listed in Teva's then-current generics catalog, which can be viewed at www.tevagenerics.com, and is provided to the State as part of the settlement, at no cost as set forth in Section III.D and Exhibit A.

Z. "*State*" means the State of Rhode Island, including all of its executive departments, agencies, divisions, boards, commissions, instrumentalities of any kind, and attorneys, including its Attorney General, and any person in his or her official capacity whether elected or appointed to serve any of the foregoing and any agency, person, or other entity seeking relief on behalf of or generally applicable to the general public of the entire State of Rhode Island.

AA. "*Subdivision(s)*" means the Rhode Island cities and towns in Exhibit B.

BB. "*Subdivision Population*" means the sum of the population of all Rhode Island Subdivisions. The population figures for Subdivisions shall be the published U.S. Census Bureau's population estimates for July 1, 2019 released May 2020. These population figures shall remain unchanged during the term of this Agreement.

CC. "*Subdivision Settlement Participation Form*" means the form attached as Exhibit D, or a substantially similar form, that Participating Subdivisions must execute and return to Teva, and which shall (1) make such Participating Subdivisions signatories to this Agreement, (2) include a full and complete release of any and all such Subdivision's claims, and (3) require the prompt dismissal with prejudice of any Released Claims that have been filed by any such Participating Subdivision.

DD. "*Teva*" means (i) Teva Pharmaceutical Industries Ltd. and, (ii) all of its respective past and present direct or indirect parents, subsidiaries, divisions, affiliates, joint ventures, predecessors, successors, assigns, and insurers (in their capacity as such), and (iii) all of the foregoing respective past and present officers, directors, members, shareholders (solely in their capacity as shareholders of the foregoing entities), partners, trustees, employees, agents, attorneys, and insurers of the foregoing entities and persons referenced in clauses (i) and (ii) above for actions or omissions that occurred during and related to their work for, or employment with, any of the foregoing entities with respect to the Released Claims.

## III. Monetary and non-Monetary Relief and Payments

A. All payments shall be made into the Rhode Island Qualified Settlement Fund.

B. Remediation and Restitution Payments by Teva.

1. Teva shall make thirteen (13) annual payments to Rhode Island for a total sum of Twenty One Million Dollars ($21,000,000) as follows, subject to the provisions in Section III.B.2:

(i) Within thirty (30) days of the Effective Date, Teva shall pay the sum of: $10,750,000;

(ii) On or before January 1, 2023, Teva shall pay the sum of: $2,250,000.00;

(iii) On or before January 1, 2024, Teva shall pay the sum of: $1,750,000.00;

(iv) On or before January 1, 2025, Teva shall pay the sum of: $1,250,000.00;

(v) On or before January 1, 2026, Teva shall pay the sum of: $1,000,000.00;

(vi) On or before January 1, 2027, Teva shall pay the sum of: $1,000,000.00;

(vii) On or before January 1, 2028, Teva shall pay the sum of: $1,000,000.00;

(viii) On or before January 1, 2029, Teva shall pay the sum of: $500,000.00;

(ix) On or before January 1, 2030, Teva shall pay the sum of: $500,000.00;

(x) On or before January 1, 2031, Teva shall pay the sum of: $250,000.00;

(xi) On or before January 1, 2032, Teva shall pay the sum of: $250,000.00;

(xii) On or before January 1, 2033, Teva shall pay the sum of: $250,000.00; and,

(xiii) On or before January 1, 2034, Teva shall pay the sum of: $250,000.00.

2. The State will use its best efforts to secure participation by all Subdivisions within Rhode Island. If by December 31, 2022, the Participating Subdivision Population does not account for at least 95% of the Subdivision Population, the Attorney General will support state legislation that would have the effect of barring recovery from Releasees by non-Participating Subdivisions. If by December 31, 2022, the Participating Subdivision Population does not account for at least 95% of the Subdivision Population, the annual payments that are due following this date shall be suspended, provided that:

a. Following a suspension of payments, Rhode Island may receive the scheduled annual payment for a specific payment year or any subsequent payment years by providing the Subdivision Settlement Participation Forms for Participating Subdivisions that account for at least 95% of the Subdivision Population. Such Subdivision Settlement Participation Forms must be provided within 90 days after a scheduled payment date for any specific payment year.

C. Use of Settlement Payments. The State of Rhode Island and Participating Subdivisions shall use the Rhode Island Abatement Funds for Opioid Remediation as set forth in Exhibits C, E and F.

D. Settlement Product.

1. Beginning on July 1, 2022 and continuing for a period of ten (10) years thereafter, the State may place orders with Teva USA for Settlement Product, to be supplied by Teva USA to one facility per order at no cost to the State ("Provision of the Settlement Product"), designated by the State, as more fully described in Exhibit A. The Parties agree that the total WAC value of all orders placed by the State under this Agreement over the ten-year period as set out below is $78,501,370.

2. Teva will provide Settlement Product free to the State as follows:

a. Naloxone Hydrochloride Nasal Spray (4 mg dosage): 50,000 kits (2 units per kit) per year for 10 years, for a total of 500,000 kits (1 million sprays); and

b. Buprenorphine & Naloxone Tablets: 700 bottles (21,000 tablets) of the 2 mg/0.5 mg dosage per year for 10 years for a total of 7,000 bottles (210,000 pills) and 6000 bottles (180,000 tablets) of the 8 mg/2 mg dosage, per year for 10 years, for a total of 60,000 bottles (1.8 million pills).

c. By agreement of the Parties, and pursuant to good faith discussions and reasonable efforts, and in response to changing public health needs, the State may request to substitute the Settlement Product the State may order at no cost for substantially similar Teva products. The State shall provide written notice to Teva and the State and Teva shall meet and confer to discuss the substitution of products.

3. If by July 1, 2023, the Participating Subdivision Population does not account for at least 95% of the Subdivision Population, the maximum Settlement Product that the State may order through this agreement shall

be reduced by a percentage point number commensurate with the percentage point difference between 100% and the Participating Subdivision Population as a percentage of the Subdivision Population. As an example, if the Participating Subdivision Population accounts for 90% of the Subdivision Population following July 1, 2023, Rhode Island may order a maximum of 45,000 Naloxone Hydrochloride Nasal Spray (4 mg dosage) kits per year, 630 bottles (18,900 tablets) of the 2 mg/0.5 mg Buprenorphine & Naloxone Tablets per year, and 5,400 bottles (162,000 tablets) of the 8 mg/2 mg Buprenorphine & Naloxone Tablets per year. Following a reduction in the maximum amount of Settlement Product Rhode Island may order, Rhode Island may restore the amount of Settlement Product it may order for a specific year or any subsequent years by providing the Subdivision Settlement Participation Forms for Participating Subdivisions that account for at least 95% of the Subdivision Population. Such Subdivision Settlement Participation Forms must be provided within 90 days after July 1 for any specific year.

4. With regard to the annual product delivery schedule, to the extent that the State's needs for each drug varies from year to year, such that the State needs a reasonably lesser quantity one year to be offset by a reasonably greater quantity the next year, Teva will use reasonable commercial efforts to be flexible in meeting that variation in demand.

5. In the event of a Force Majeure Event, Teva shall promptly provide written notice to the State. Teva and the State shall meet and confer within seven (7) days of such written notice to establish a commercially reasonable plan to resolve any inability to supply as quickly as reasonably possible.

6. If Teva ceases the manufacture and/or distribution of one or more of the Settlement Products unrelated to a Force Majeure Event, Teva shall promptly provide written notice to the State. Teva and the State shall meet and confer within seven (7) days of such written notice. In such an event, Teva shall provide the State with substantially similar products.

E. Upon execution of the Agreement, the State of Rhode Island shall file the Rhode Island Consent Judgment at Exhibit H with the Court, including a dismissal with prejudice of its Claims against Teva.

## IV. Injunctive Relief

A. The State and Teva agree to the injunctive relief as specified in Exhibit G.

## V. Release

A. *Scope*. As of the Effective Date, the Released Entities will be released and forever discharged from all of the Releasors' Released Claims. The State (for itself) absolutely, unconditionally, and irrevocably covenants not to bring, file, or claim, or to cause, assist in bringing, or permit to be brought, filed, or claimed, or to otherwise seek to establish liability for any Released Claims for Covered Conduct against any Released Entity in any forum whatsoever. The releases provided for in the Agreement are intended by the Parties to be broad and shall be interpreted so as to give the Released Entities the broadest possible bar against any liability arising from or relating in any way to the Released Claims and extend to the full extent of the power of the State and its Attorney General, and each Releasor to release claims. The Release shall be a complete bar to any Released Claim.

B. *Claim-Over*. In the event that any Releasor obtains a judgment with respect to Non-Party Covered Conduct against a Non-Released Entity that does not contain a prohibition like that in subsection V.I (including in any bankruptcy proceeding), and such Non-Released Entity asserts a Claim-Over against a Released Entity related to the Released Claims, that Releasor and Teva shall take the following actions to ensure that the Released Entities do not pay more with respect to the Released Claims to Releasors or to Non-Released Entities than the amounts owed under this Settlement Agreement by Teva:

a. Teva shall notify that Releasor of the Claim-Over within sixty (60) days of the assertion of the Claim-Over or sixty (60) days of the Effective Date of this Settlement Agreement, whichever is later;

b. Teva and that Releasor shall meet and confer concerning the means to hold Released Entities harmless and ensure that Released Entities are not required to make any payment with respect to the Released Claims (beyond the amounts and product provisions owed by Teva under this Settlement Agreement).

c. That Releasor and Teva shall take steps sufficient and permissible under Rhode Island law to hold Released Entities harmless from the Claim-Over with respect to Released Claims and ensure Released Entities are not required to make any payment with respect to the Released Claims (beyond the amounts and product provisions owed by Teva under this Settlement Agreement). Such steps may include, where permissible, filing of motions to dismiss or such other appropriate motion by Teva or Released Entities, and supported by Releasors, in response to any claim filed in litigation or arbitration or such other reasonable actions that ensure Teva is not required to pay more to Releasors with respect to Released

Claims than the amounts owed or product provided by Teva under this Agreement.

d. For the removal of doubt, Teva's payment and provision obligations under this agreement shall not be disrupted or delayed in the event of a Claim-Over, except by agreement of the parties to this Agreement.

C. *General Release*. In connection with the releases provided for in the Agreement, the State (for itself and its Releasors), and each Participating Subdivision (for itself and its Releasors) expressly waive, release, and forever discharge any and all provisions, rights, and benefits conferred by any law of any state or territory of the United States or other jurisdiction, or principle of common law, which is similar, comparable, or equivalent to § 1542 of the California Civil Code, which reads:

> **General Release; extent.** A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.

A Releasor may thereafter discover facts other than or different from those which it knows, believes, or assumes to be true with respect to the Released Claims, but the State (for itself and its Releasors) and each Participating Subdivision (for itself and its Releasors) expressly waive and fully, finally, and forever settle, release and discharge, upon the Effective Date, any and all Released Claims that may exist as of such date but which Releasors do not know or suspect to exist, whether through ignorance, oversight, error, negligence or through no fault whatsoever, and which, if known, would materially affect the State's decision to enter into the Agreement or the Participating Subdivisions' decision to participate in the Agreement.

D. *Cooperation*. Releasors (i) will not encourage any person or entity to bring or maintain any Released Claim against any Released Entity and (ii) will reasonably cooperate with and not oppose any effort by a Released Entity to secure the prompt dismissal of any and all Released Claims. The State shall use its best efforts to secure releases consistent with this Section from all Subdivisions.

E. *Res Judicata*. Nothing in the Agreement shall be deemed to reduce the scope of the res judicata or claim preclusive effect that the settlement memorialized in the Agreement, and/or any Consent Judgment or other judgment entered on the Agreement, gives rise to under applicable law.

F. *Representation and Warranty*. The State, by and through its Attorney General, expressly represents and warrants that it has the authority to settle and release all

Released Claims of the State and its executive departments and agencies. Executive departments and agencies are those that are under the executive authority or direct control of the State's Governor.

G. *Effectiveness.* The releases set forth in the Agreement shall not be impacted in any way by any dispute that exists, has existed, or may later exist between or among the Releasors. Nor shall such releases be impacted in any way by any current or future law, regulation, ordinance, or court or agency order limiting, seizing, or controlling the distribution or use of the Qualified Settlement Fund or any portion thereof, or by the enactment of future laws, or by any seizure of the Qualified Settlement Fund or any portion thereof.

H. *Non-Released Claims.* Notwithstanding the foregoing or anything in the definition of Released Claims, the Agreement does not waive, release or limit any criminal liability, Claims for any outstanding liability under any tax or securities law, Claims against parties who are not Released Entities, Claims by individuals for damages for any alleged personal injuries arising out of their own use of any opioid product and any claims arising under the Agreement for enforcement of the Agreement.

I. *Contribution/Indemnity Prohibited.* No Released Entity shall seek to recover for amounts paid under this Agreement based on indemnification, contribution, or any other theory from a manufacturer, pharmacy, hospital, pharmacy benefit manager, health insurer, third-party vendor, trade association, distributor, or health care practitioner, provided that a Released Entity shall be relieved of this prohibition with respect to any entity that asserts a Claim-Over against it. For the avoidance of doubt, nothing herein shall prohibit a Released Entity from recovering amounts owed pursuant to insurance contracts.

## VI. Participation by Subdivisions

A. *Requirements for Becoming a Participating Subdivision:* A Subdivision in the State may become a Participating Subdivision either by executing a Subdivision Settlement Participation Form and, for a Litigating Subdivision, upon prompt dismissal of its legal action or by having its claims extinguished by operation of law or released by the State's Office of the Attorney General.

B. *Notice.* The State's Office of the Attorney General shall send notice to all Litigating Subdivisions eligible to participate in the settlement and the requirements for participation. Such notice may include publication, email, and other standard forms of notification.

C. *Non-Participating Subdivisions.* Non-Participating Subdivisions shall not receive any portion of settlement payments from Teva under this Agreement.

## VII. Attorney Fee and Cost Payments

A. *Teva Attorney Fee and Litigation Expenses Payment.* The Office of the Attorney has engaged outside counsel in the matter pursuant to a contingency fee agreement. The Office of the Attorney General has retained absolute and total control over all critical decisions made throughout this litigation. Case management authority of the Attorney General, pursuant to its agreement with outside counsel, has been final, sole, and unreviewable. A senior member of the Attorney General's staff has been personally involved in all stages of this litigation. The below fee provision is reflective of (1) a reasonable number of hours worked multiplied by reasonable hourly rates, (2) the time and labor required, the novelty and difficulty of the questions involved, and the skill requisite to perform the legal services properly, (3) the likelihood that the acceptance of engagement precluded other employment, (4) fees customarily charged in this locality for similar legal services, (5) the amount involved and the results obtained, (6) the time limitations imposed by the circumstances, (7) the nature and length of the professional relationship between outside counsel and the Office of the Attorney General, (8) the experience, reputation, and ability of the outside counsel performing the services, (9) the contingency fee arrangement.

B. The terms for outside counsel attorney fee and cost payments to be paid by Teva are as follows:

1. Teva shall pay the State of Rhode Island's outside counsel fees associated with the litigation of the Claims against Teva the sum of: $5,460,349.00.

2. Teva shall pay the State of Rhode Island's reasonable costs associated with the litigation of the Claims against Teva up to a cap of $3 million, to be reimbursed by Teva within thirty (30) days after the Effective Date of this Agreement. Rhode Island outside counsel shall submit itemized expenses for reimbursement within five (5) days of Effective Date of this Agreement.

    a. *Dispute resolution.* Any dispute over reimbursement of reasonable costs associated with litigation of Claims against Teva shall be submitted to Special Master David R. Cohen or Eric Green of Resolutions, LLC for resolution, which shall be final, binding and non-appealable.

C. This Agreement does not prohibit Litigating Subdivisions or their counsel from recovering attorney fees under a potential Teva Global Resolution as described in Section X.D, should such a Global Resolution provide a mechanism to pay attorney fees.

## VIII. Bankruptcy

A. *Bankruptcy.* Nothing in this Agreement shall preclude the State or any Participating Subdivision from receiving a distribution from a potential bankruptcy of Teva to the extent that the State or Participating Subdivision has a right to receive a payment or distribution in accordance with this Agreement. Subject to the terms of this Agreement (including all releases, covenants and payment terms contained herein), all of the State's and the Participating Subdivisions' rights with respect to any bankruptcy case of Teva are specifically reserved by the State and the Participating Subdivisions. If for any reason, the State or any Participating Subdivision must remit any portion of the Settlement Amount to a bankruptcy court or other party as a result of the commencement of a case with respect to Teva under Title 11 of the United States Code (the "Bankruptcy Code") then Teva shall make such payment to the State as soon as reasonably practicable.

## IX. Enforcement and Dispute Resolution

A. *Enforceability.* The terms of the Agreement and the Rhode Island Consent Judgment will be enforceable solely by the State of Rhode Island and Teva. Participating Subdivisions shall not have enforcement rights against Teva with respect to the Agreement or Rhode Island Consent Judgment except as to payments that would be allocated under the Rhode Island Memorandum of Understanding for subdivision use. The State of Rhode Island shall establish a process for Participating Subdivisions to notify it of any perceived violations of the Agreement or Rhode Island Consent Judgment.

B. *Jurisdiction.* Teva consents to the jurisdiction of the Court for the limited purpose of enforcing this Agreement and the Rhode Island Consent Judgment.

C. *Dispute Resolution.* The parties to a dispute shall promptly meet and confer in good faith to resolve any dispute. If the parties cannot resolve the dispute informally, and unless otherwise agreed in writing, the dispute shall be resolved in the Court.

## X. Miscellaneous

A. *Taxes.* Each of the Parties acknowledges, agrees, and understands that it is its intention that, for purposes of Section 162(f) of the Internal Revenue Code, the provision of the Settlement Amount and the Settlement Product by Teva (other than amounts directed to attorneys' fees and costs) constitutes restitution for damage or harm allegedly caused by the potential violation of a law and/or is an amount paid to come into compliance with the law. The Parties acknowledge, agree and understand that, other than the amounts directed to attorneys' fees and

costs, no other portion of the Settlement Amount and/or Settlement Product represents reimbursement to the State, any Participating Subdivision or other person or entity for the costs of any investigation or litigation, and no portion of the Settlement Amount and/or Settlement Product represents or should properly be characterized as the payment of fines, penalties, or other punitive assessments, and furthermore, the combined value of the Settlement Amount and the Settlement Product constitute less than one times damages sought by the State. The State and every Participating Subdivision shall complete and file Form 1098-F with the Internal Revenue Service, identifying the Settlement Amount and the Settlement Product (other than amounts directed to attorney fees and costs) as remediation/restitution amounts, and shall furnish Copy B of such Form 1098-F to Teva and shall otherwise fully comply with the requirements of Section 162(f) and Section 6050X of the Internal Revenue Code and all treasury regulations relating to those provisions of the Internal Revenue Code. Teva makes no warranty or representation to the State or any Participating Subdivision as to the tax consequences of the Settlement Amount or the Settlement Product or any portion thereof.

B. Nothing in this Agreement shall be construed to authorize or require any action by Teva in violation of applicable federal, state, or other laws.

C. *No Admission.* Teva does not admit liability, fault, or wrongdoing. Neither this Agreement nor the Rhode Island Consent Judgment shall be considered, construed or represented to be (1) an admission, concession or evidence of liability or wrongdoing or (2) a waiver or any limitation of any defense otherwise available to Teva. It is the understanding and intent of the parties that this Agreement shall not be entered into evidence in any other action against Teva, among other reasons, because it is not relevant to such action. For the avoidance of any doubt, nothing herein shall prohibit Teva from entering this Agreement into evidence in any litigation or arbitration concerning Teva's right to coverage under an insurance contract

D. *Most Favored Nation.* If, after execution of this Agreement, there is a collective nationwide resolution—through settlement, bankruptcy or other mechanism—of substantially all claims against Teva brought by states, counties, and municipalities (a "Global Resolution") the following shall apply:

1. *Settlement Payment True Up.* If the State's cash payment allocation would be greater under the Global Resolution than the Settlement Amount under this Agreement on a net present value basis (calculated based on a discount rate of 7%), then Teva shall pay the State the difference between the Settlement Amount and the amount that would have been allocated to the State under the terms and in accordance with any such Global Resolution;

2. *Payment Term True Up.* If the cash Payment Term under the Global Resolution would be shorter than the thirteen (13) year cash Payment Term under this Agreement, then the State shall be entitled to the benefit of the shorter Payment Term under the Global Resolution.

3. *Settlement Product True Up.* Separate and apart from the value of any Settlement Payment amounts, if the WAC value of the State's allocation of Settlement Product under the Global Resolution would be greater than the WAC value of the State's allocation of Settlement Product under this Agreement, then Teva shall provide to the State such additional Settlement Product as needed to make up the difference in accordance with the terms of Exhibit A. For purposes of this provision, the Parties agree that the total WAC value of the Settlement Product under this Agreement is $78,501,370.

E. *Modification.* This Agreement may be modified by a written agreement of the Parties or, in the case of the Consent Judgment, by court proceedings resulting in a modified judgment of the Court. Modifications must be in writing and agreed to by all of the parties to be enforceable.

F. Any failure by any party to this Agreement to insist upon the strict performance by any other party of any of the provisions of this Agreement shall not be deemed a waiver of any of the provisions of this Agreement, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

G. *Entire Agreement.* This Agreement represents the full and complete terms of the settlement entered into by the Parties hereto, except as provided herein. In any action undertaken by the Parties, no prior versions of this Agreement and no prior versions of any of its terms may be introduced for any purpose whatsoever.

H. *Counterparts.* This Agreement may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

I. *Notice.* All notices under this Agreement shall be provided to the following via email and Overnight Mail:

*For Defendant:*

Teva Pharmaceuticals
Attn: General Counsel's Office
400 Interpace Parkway
Parsippany, NJ 07054

*Copy to Teva's attorneys at:*

Eric W. Sitarchuk
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
eric.sitarchuk@morganlewis.com

Rebecca J. Hillyer
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103-2921
rebecca.hillyer@morganlewis.com

*For the Attorney General:*

Deputy Attorney General
Adi Goldstein
Office of the Attorney General
150 South Main Street
Providence, RI 02903
agoldstein@riag.ri.gov

**APPROVED:**

DATED: 3.21.22

TEVA PHARMACEUTICALS

By: _____
Name: Eric W. Sitarchuk
Rebecca J. Hillyer
Title: Morgan Lewis & Bockius LLP
*Attorneys for Teva*

DATED: 3/21/2022

THE STATE OF RHODE ISLAND

PETER F. NERONHA
ATTORNEY GENERAL

By: _____
Name: Adi Goldstein
Title: Deputy Attorney General
*Attorney for the State of Rhode Island*

# Exhibit A

# State Plan for Acceptance and Delivery of Settlement Product

## Exhibit A

## State Plan for Acceptance and Delivery of Settlement Product

### Orders to TEVA USA

The Rhode Island Executive Office of Health and Human Services ("EOHHS"), on behalf of the State, shall have the right to place periodic orders, not to exceed four (4) quarterly orders per year, to Teva USA for fulfillment of Settlement Product over a period of ten (10) years from July 1, 2022. Orders submitted to Teva USA on behalf of the State pursuant to this Settlement Agreement shall in all respects be processed and filled by Teva USA as though such orders had been submitted by Teva USA's regular paying customers except to the extent inconsistent with the terms of the Settlement Agreement and the terms herein.

The total volume of Settlement Product requested shall not exceed the following quantities during a twelve-month period:

- Naloxone Hydrochloride Nasal Spray (4 mg dosage): 50,000 kits (2 units per kit) (to be ordered only in batches of 50,000 kits or 25,000 kits unless otherwise agreed to by the Parties);
- Buprenorphine & Naloxone Tablets (2 mg/0.5 mg dosage): 700 bottles (21,000 tablets); and
- Buprenorphine & Naloxone Tablets (8 mg/2 mg dosage): 6000 bottles (180,000 tablets).

The Settlement Product order from the State shall be in writing and directed to Teva USA's affiliate Anda, Inc., 2915 Weston Road, Weston, FL 33331, Attention: Patrick Cochrane, patrick.cochrane@andanet.com and Anthony Mihelich, anthony.mihelich@andanet.com. Each Settlement Product order must identify the quantity of the Settlement Product, the available annual amount remaining for fulfillment, and the total quantity of Settlement Product delivered by Teva USA as of the date of the order. Teva USA shall respond to the State's order request within seven (7) calendar days confirming the order.

Teva USA will use its commercially reasonable efforts to ship the order directly to the appropriately licensed facility designated by the State within six (6) months of the order at no cost to the State and shall provide the State with estimated delivery dates for receipt of the Settlement Product. Notwithstanding the foregoing, for each order from the State following the initial order, Teva USA agrees that it will use its good faith efforts to ship Settlement Product to the facility designated by the State within ninety (90) days of the order.

EOHHS shall designate in writing a State official that will place the State's Settlement Product orders (the "Designated Official"). The State may change the Designated Official by notifying Teva USA in writing.

**Delivery to State-Designated Facility**

Delivery of the Settlement Product shall occur no more than five (5) business days after the shipment date. Should delivery within this deadline not occur, Teva USA agrees to notify the State in writing and to work in good faith to resolve shipping or delivery issues that may arise.

Shipping shall occur in the same manner that Teva USA regularly ships this Settlement Product and any damages to the Settlement Product or other shipping damages or liability arising prior to receipt of the Settlement Product by the State shall be fully the responsibility of Teva USA. Should damage to Settlement Product occur during shipping, Teva USA agrees to re-ship the amount damaged promptly and at no cost to the State.

The State shall designate one location per order that is appropriately licensed with the Drug Enforcement Administration to receive Controlled Substances for delivery of Settlement Product by Teva USA and identify the location in the Settlement Product order. In writing and no later than the State's initial Settlement Product order, the Designated Official will designate the appropriately licensed facility in Rhode Island that will receive the Settlement Product on behalf of the State. The State reserves the right to designate a different delivery location within Rhode Island during the pendency of the settlement agreement at its discretion.

Should the State determine that an alternate state facility or agency will receive the Settlement Product during the pendency of the settlement, the State shall notify Teva USA and its affiliate Anda, Inc. in writing through the Settlement Product order.

Teva USA shall deliver to any facility in Rhode Island identified by the State but may not be required to deliver Settlement Product to more than one location per order for any given delivery.

The State agrees to receive the Settlement Product in a location with appropriate storage accommodations and will comply with all applicable state and federal laws surrounding receipt of the Settlement Product.

The State shall inspect the Settlement Product within five (5) business days upon arrival at the state facility. If the State identifies damages to the Settlement Product during the inspection, Teva USA agrees to work in good faith to replace the damaged Settlement Product promptly.

Delivery of the Settlement Product is complete when Teva USA delivers all units of a particular order to the state facility and when both parties or their designees sign an invoice confirming the amount of units of Settlement Product received by the State.

**Distribution by State**

The State intends to distribute the Settlement Product to appropriate state agencies, law enforcement agencies, first responders, community organizations, and healthcare providers throughout Rhode Island ("Recipients"). The time, place, and manner of distribution of the Settlement Product by the State will be determined solely by the State. The State will comply with any state or federal laws regarding the distribution of the Settlement Product.

The State retains the right to alter its distribution plan according to the State's needs, including the right to store the Settlement Product at a state facility for any length of time. The State may distribute the Settlement Product as it deems best to address the opioid-related public health crisis in Rhode Island, and alteration of distribution to Recipients shall be at the sole discretion of the State without regard to the preferences or recommendations of Teva USA.

# Exhibit B

# Agreed List of All Rhode Island State Subdivisions

**EXHIBIT B**

**Agreed List of All Rhode Island State Subdivisions**

**Litigating Subdivisions**

1. Barrington (RI), Town of
2. Bristol (RI), Town of
3. Burrillville (RI), Town of
4. Central Falls (RI), City of
5. Charlestown (RI), Town of
6. Coventry (RI), Town of
7. Cranston (RI), City of
8. Cumberland (RI), Town of
9. East Greenwich (RI), Town of
10. East Providence (RI), City of
11. Foster (RI), Town of
12. Glocester (RI), Town of
13. Hopkinton (RI), Town of
14. Jamestown (RI), Town of
15. Johnston (RI), Town of
16. Middletown (RI), Town of
17. Narragansett (RI), Town of
18. Newport (RI), City of
19. North Kingstown (RI), Town of
20. North Providence (RI), Town of
21. Pawtucket (RI), City of
22. Portsmouth (RI), Town of
23. Providence (RI), City of
24. Richmond (RI), Town of
25. Scituate (RI), Town of
26. Smithfield (RI), Town of
27. South Kingstown (RI), Town of
28. Warren (RI), Town of
29. Warwick (RI), City of
30. West Greenwich (RI), Town of
31. West Warwick (RI), Town of
32. Westerly (RI), Town of
33. Woonsocket (RI), City of

**Non-Litigating Subdivisions**

34. Exeter (RI), Town of
35. Lincoln (RI), Town of
36. Little Compton (RI), Town of
37. New Shoreham (RI), Town of
38. North Smithfield (RI), Town of
39. Tiverton (RI), Town of

# Exhibit C

# List of Opioid Remediation Uses

**EXHIBIT C**

**List of Opioid Remediation Uses**

**Schedule A**
**Core Strategies**

The State and Participating Subdivisions shall choose from among the abatement strategies listed in Schedule B. However, priority shall be given to the following core abatement strategies ("*Core Strategies*").

A. **NALOXONE OR OTHER FDA-APPROVED DRUG TO REVERSE OPIOID OVERDOSES**

1. Expand training for first responders, schools, community support groups and families; and

2. Increase distribution to individuals who are uninsured or whose insurance does not cover the needed service.

B. **MEDICATION-ASSISTED TREATMENT ("*MAT*") DISTRIBUTION AND OTHER OPIOID-RELATED TREATMENT**

1. Increase distribution of MAT to individuals who are uninsured or whose insurance does not cover the needed service;

2. Provide education to school-based and youth-focused programs that discourage or prevent misuse;

3. Provide MAT education and awareness training to healthcare providers, EMTs, law enforcement, and other first responders; and

4. Provide treatment and recovery support services such as residential and inpatient treatment, intensive outpatient treatment, outpatient therapy or counseling, and recovery housing that allow or integrate medication and with other support services.

C. **PREGNANT & POSTPARTUM WOMEN**

1. Expand Screening, Brief Intervention, and Referral to Treatment ("*SBIRT*") services to non-Medicaid eligible or uninsured pregnant women;

2. Expand comprehensive evidence-based treatment and

recovery services, including MAT, for women with co-occurring Opioid Use Disorder ("*OUD*") and other Substance Use Disorder ("*SUD*")/Mental Health disorders for uninsured individuals for up to 12 months postpartum; and

3. Provide comprehensive wrap-around services to individuals with OUD, including housing, transportation, job placement/training, and childcare.

D. **EXPANDING TREATMENT FOR NEONATAL ABSTINENCE SYNDROME ("*NAS*")**

1. Expand comprehensive evidence-based and recovery support for NAS babies;

2. Expand services for better continuum of care with infant-need dyad; and

3. Expand long-term treatment and services for medical monitoring of NAS babies and their families.

E. **EXPANSION OF WARM HAND-OFF PROGRAMS AND RECOVERY SERVICES**

1. Expand services such as navigators and on-call teams to begin MAT in hospital emergency departments;

2. Expand warm hand-off services to transition to recovery services;

3. Broaden scope of recovery services to include co-occurring SUD or mental health conditions;

4. Provide comprehensive wrap-around services to individuals in recovery, including housing, transportation, job placement/training, and childcare; and

5. Hire additional social workers or other behavioral health workers to facilitate expansions above.

F. **TREATMENT FOR INCARCERATED POPULATION**

1. Provide evidence-based treatment and recovery support, including MAT for persons with OUD and co-occurring SUD/MH disorders within and transitioning out of the criminal justice system; and

2. Increase funding for jails to provide treatment to inmates with OUD.

G. **PREVENTION PROGRAMS**

1. Funding for media campaigns to prevent opioid use (similar to the FDA's "Real Cost" campaign to prevent youth from misusing tobacco);

2. Funding for evidence-based prevention programs in schools;

3. Funding for medical provider education and outreach regarding best prescribing practices for opioids consistent with the 2016 CDC guidelines, including providers at hospitals (academic detailing);

4. Funding for community drug disposal programs; and

5. Funding and training for first responders to participate in pre-arrest diversion programs, post-overdose response teams, or similar strategies that connect at-risk individuals to behavioral health services and supports.

H. **EXPANDING SYRINGE SERVICE PROGRAMS**

1. Provide comprehensive syringe services programs with more wrap-around services, including linkage to OUD treatment, access to sterile syringes and linkage to care and treatment of infectious diseases.

I. **EVIDENCE-BASED DATA COLLECTION AND RESEARCH ANALYZING THE EFFECTIVENESS OF THE ABATEMENT STRATEGIES WITHIN THE STATE**

**Schedule B**
**Approved Uses**

Support treatment of Opioid Use Disorder (OUD) and any co-occurring Substance Use Disorder or Mental Health (SUD/MH) conditions through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the following:

| PART ONE: TREATMENT |
|---|

## A. TREAT OPIOID USE DISORDER (OUD)

Support treatment of Opioid Use Disorder ("*OUD*") and any co-occurring Substance Use Disorder or Mental Health ("*SUD/MH*") conditions through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, those that:[13]

1. Expand availability of treatment for OUD and any co-occurring SUD/MH conditions, including all forms of Medication-Assisted Treatment ("*MAT*") approved by the U.S. Food and Drug Administration.

2. Support and reimburse evidence-based services that adhere to the American Society of Addiction Medicine ("*ASAM*") continuum of care for OUD and any co-occurring SUD/MH conditions.

3. Expand telehealth to increase access to treatment for OUD and any co-occurring SUD/MH conditions, including MAT, as well as counseling, psychiatric support, and other treatment and recovery support services.

4. Improve oversight of Opioid Treatment Programs ("*OTPs*") to assure evidence-based or evidence-informed practices such as adequate methadone dosing and low threshold approaches to treatment.

5. Support mobile intervention, treatment, and recovery services, offered by qualified professionals and service providers, such as peer recovery coaches, for persons with OUD and any co-occurring SUD/MH conditions and for persons who have experienced an opioid overdose.

6. Provide treatment of trauma for individuals with OUD (*e.g.*, violence, sexual assault, human trafficking, or adverse childhood experiences) and family members (*e.g.*, surviving family members after an overdose or overdose fatality), and training of health care personnel to identify and address such trauma.

7. Support evidence-based withdrawal management services for people with OUD and any co-occurring mental health conditions.

8. Provide training on MAT for health care providers, first responders, students, or other supporting professionals, such as peer recovery coaches or recovery outreach specialists, including telementoring to assist community-based providers in rural or underserved areas.

9. Support workforce development for addiction professionals who work with persons with OUD and any co-occurring SUD/MH conditions.

10. Offer fellowships for addiction medicine specialists for direct patient care, instructors, and clinical research for treatments.

11. Offer scholarships and supports for behavioral health practitioners or workers involved in addressing OUD and any co-occurring SUD/MH or mental health conditions, including, but not limited to, training, scholarships, fellowships, loan repayment programs, or other incentives for providers to work in rural or underserved areas.

12. Provide funding and training for clinicians to obtain a waiver under the federal Drug Addiction Treatment Act of 2000 ("*DATA 2000*") to prescribe MAT for OUD, and provide technical assistance and professional support to clinicians who have obtained a DATA 2000 waiver.

13. Disseminate of web-based training curricula, such as the American Academy of Addiction Psychiatry's Provider Clinical Support Service–Opioids web-based training curriculum and motivational interviewing.

14. Develop and disseminate new curricula, such as the American Academy of Addiction Psychiatry's Provider Clinical Support Service for Medication–Assisted Treatment.

## B. SUPPORT PEOPLE IN TREATMENT AND RECOVERY

Support people in recovery from OUD and any co-occurring SUD/MH conditions through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the programs or strategies that:

1. Provide comprehensive wrap-around services to individuals with OUD and any co-occurring SUD/MH conditions, including housing, transportation, education, job placement, job training, or childcare.

2. Provide the full continuum of care of treatment and recovery services for OUD and any co-occurring SUD/MH conditions, including supportive housing, peer support services and counseling, community navigators, case management, and connections to community-based services.

3. Provide counseling, peer-support, recovery case management and residential treatment with access to medications for those who need it to persons with OUD and any co-occurring SUD/MH conditions.

4. Provide access to housing for people with OUD and any co-occurring SUD/MH conditions, including supportive housing, recovery housing, housing assistance programs, training for housing providers, or recovery housing programs that allow or integrate FDA-approved mediation with other support services.

5. Provide community support services, including social and legal services, to assist in deinstitutionalizing persons with OUD and any co-occurring SUD/MH conditions.

6. Support or expand peer-recovery centers, which may include support groups, social events, computer access, or other services for persons with OUD and any co-occurring SUD/MH conditions.

7. Provide or support transportation to treatment or recovery programs or services for persons with OUD and any co-occurring SUD/MH conditions.

8. Provide employment training or educational services for persons in treatment for or recovery from OUD and any co-occurring SUD/MH conditions.

9. Identify successful recovery programs such as physician, pilot, and college recovery programs, and provide support and technical assistance to increase the number and capacity of high-quality programs to help those in recovery.

10. Engage non-profits, faith-based communities, and community coalitions to support people in treatment and recovery and to support family members in their efforts to support the person with OUD in the family.

11. Provide training and development of procedures for government staff to appropriately interact and provide social and other services to individuals with or in recovery from OUD, including reducing stigma.

12. Support stigma reduction efforts regarding treatment and support for persons with OUD, including reducing the stigma on effective treatment.

13. Create or support culturally appropriate services and programs for persons with OUD and any co-occurring SUD/MH conditions, including new Americans.

14. Create and/or support recovery high schools.

15. Hire or train behavioral health workers to provide or expand any of the services or supports listed above.

## C. CONNECT PEOPLE WHO NEED HELP TO THE HELP THEY NEED (CONNECTIONS TO CARE)

Provide connections to care for people who have—or are at risk of developing—OUD and any co-occurring SUD/MH conditions through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, those that:

1. Ensure that health care providers are screening for OUD and other risk factors and know how to appropriately counsel and treat (or refer if necessary) a patient for OUD treatment.

2. Fund SBIRT programs to reduce the transition from use to disorders, including SBIRT services to pregnant women who are uninsured or not eligible for Medicaid.

3. Provide training and long-term implementation of SBIRT in key systems (health, schools, colleges, criminal justice, and probation), with a focus on youth and young adults when transition from misuse to opioid disorder is common.

4. Purchase automated versions of SBIRT and support ongoing costs of the technology.

5. Expand services such as navigators and on-call teams to begin MAT in hospital emergency departments.

6. Provide training for emergency room personnel treating opioid overdose patients on post-discharge planning, including community referrals for MAT, recovery case management or support services.

7. Support hospital programs that transition persons with OUD and any co-occurring SUD/MH conditions, or persons who have experienced an opioid overdose, into clinically appropriate follow-up care through a bridge clinic or similar approach.

8. Support crisis stabilization centers that serve as an alternative to hospital emergency departments for persons with OUD and any co-occurring SUD/MH conditions or persons that have experienced an opioid overdose.

9. Support the work of Emergency Medical Systems, including peer support specialists, to connect individuals to treatment or other appropriate services following an opioid overdose or other opioid-related adverse event.

10. Provide funding for peer support specialists or recovery coaches in emergency departments, detox facilities, recovery centers, recovery housing, or similar settings; offer services, supports, or connections to care to persons with OUD and any co-occurring SUD/MH conditions or to persons who have experienced an opioid overdose.

11. Expand warm hand-off services to transition to recovery services.

12. Create or support school-based contacts that parents can engage with to seek immediate treatment services for their child; and support prevention, intervention, treatment, and recovery programs focused on young people.

13. Develop and support best practices on addressing OUD in the workplace.

14. Support assistance programs for health care providers with OUD.

15. Engage non-profits and the faith community as a system to support outreach for treatment.

16. Support centralized call centers that provide information and connections to appropriate services and supports for persons with OUD and any co-occurring SUD/MH conditions.

## D. ADDRESS THE NEEDS OF CRIMINAL JUSTICE-INVOLVED PERSONS

Address the needs of persons with OUD and any co-occurring SUD/MH conditions who are involved in, are at risk of becoming involved in, or are transitioning out of the criminal justice system through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, those that:

1. Support pre-arrest or pre-arraignment diversion and deflection strategies for persons with OUD and any co-occurring SUD/MH conditions, including established strategies such as:

    1. Self-referral strategies such as the Angel Programs or the Police Assisted Addiction Recovery Initiative ("*PAARI*");

    2. Active outreach strategies such as the Drug Abuse Response Team ("*DART*") model;

    3. "Naloxone Plus" strategies, which work to ensure that individuals who have received naloxone to reverse the effects of an overdose are then linked to treatment programs or other appropriate services;

    4. Officer prevention strategies, such as the Law Enforcement Assisted Diversion ("*LEAD*") model;

    5. Officer intervention strategies such as the Leon County, Florida Adult Civil Citation Network or the Chicago Westside Narcotics Diversion to Treatment Initiative; or

    6. Co-responder and/or alternative responder models to address OUD-related 911 calls with greater SUD expertise.

2. Support pre-trial services that connect individuals with OUD and any co-occurring SUD/MH conditions to evidence-informed treatment, including MAT, and related services.

3. Support treatment and recovery courts that provide evidence-based options for persons with OUD and any co-occurring SUD/MH conditions.

4. Provide evidence-informed treatment, including MAT, recovery support, harm reduction, or other appropriate services to individuals with OUD and any co-occurring SUD/MH conditions who are incarcerated in jail or prison.

5. Provide evidence-informed treatment, including MAT, recovery support, harm reduction, or other appropriate services to individuals with OUD and any co-occurring SUD/MH conditions who are leaving jail or prison or have recently left jail or prison, are on probation or parole, are under community corrections supervision, or are in re-entry programs or facilities.

6. Support critical time interventions ("*CTI*"), particularly for individuals living with dual-diagnosis OUD/serious mental illness, and services for individuals who face immediate risks and service needs and risks upon release from correctional settings.

7. Provide training on best practices for addressing the needs of criminal justice-involved persons with OUD and any co-occurring SUD/MH conditions to law enforcement, correctional, or judicial personnel or to providers of treatment, recovery, harm reduction, case management, or other services offered in connection with any of the strategies described in this section.

## E. ADDRESS THE NEEDS OF PREGNANT OR PARENTING WOMEN AND THEIR FAMILIES, INCLUDING BABIES WITH NEONATAL ABSTINENCE SYNDROME

Address the needs of pregnant or parenting women with OUD and any co-occurring SUD/MH conditions, and the needs of their families, including babies with neonatal abstinence syndrome ("*NAS*"), through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, those that:

1. Support evidence-based or evidence-informed treatment, including MAT, recovery services and supports, and prevention services for pregnant women—or women who could become pregnant—who have OUD and any co-occurring SUD/MH conditions, and other measures to educate and provide support to families affected by Neonatal Abstinence Syndrome.

2. Expand comprehensive evidence-based treatment and recovery services, including MAT, for uninsured women with OUD and any co-occurring SUD/MH conditions for up to 12 months postpartum.

3. Provide training for obstetricians or other healthcare personnel who work with pregnant women and their families regarding treatment of OUD and any co-occurring SUD/MH conditions.

4. Expand comprehensive evidence-based treatment and recovery support for NAS babies; expand services for better continuum of care with infant-need dyad; and expand long-term treatment and services for medical monitoring of NAS babies and their families.

5. Provide training to health care providers who work with pregnant or parenting women on best practices for compliance with federal requirements that children born with NAS get referred to appropriate services and receive a plan of safe care.

6. Provide child and family supports for parenting women with OUD and any co-occurring SUD/MH conditions.

7. Provide enhanced family support and child care services for parents with OUD and any co-occurring SUD/MH conditions.

8. Provide enhanced support for children and family members suffering trauma as a result of addiction in the family; and offer trauma-informed behavioral health treatment for adverse childhood events.

9. Offer home-based wrap-around services to persons with OUD and any co-occurring SUD/MH conditions, including, but not limited to, parent skills training.

10. Provide support for Children's Services—Fund additional positions and services, including supportive housing and other residential services, relating to children being removed from the home and/or placed in foster care due to custodial opioid use.

PART TWO: PREVENTION

## F. PREVENT OVER-PRESCRIBING AND ENSURE APPROPRIATE PRESCRIBING AND DISPENSING OF OPIOIDS

Support efforts to prevent over-prescribing and ensure appropriate prescribing and dispensing of opioids through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the following:

1. Funding medical provider education and outreach regarding best prescribing practices for opioids consistent with the Guidelines for Prescribing Opioids for Chronic Pain from the U.S. Centers for Disease Control and Prevention, including providers at hospitals (academic detailing).

2. Training for health care providers regarding safe and responsible opioid prescribing, dosing, and tapering patients off opioids.

3. Continuing Medical Education (CME) on appropriate prescribing of opioids.

4. Providing Support for non-opioid pain treatment alternatives, including training providers to offer or refer to multi-modal, evidence-informed treatment of pain.

5. Supporting enhancements or improvements to Prescription Drug Monitoring Programs ("*PDMPs*"), including, but not limited to, improvements that:

1. Increase the number of prescribers using PDMPs;

2. Improve point-of-care decision-making by increasing the quantity, quality, or format of data available to prescribers using PDMPs, by improving the interface that prescribers use to access PDMP data, or both; or

3. Enable states to use PDMP data in support of surveillance or intervention strategies, including MAT referrals and follow-up for individuals identified within PDMP data as likely to experience OUD in a manner that complies with all relevant privacy and security laws and rules.

6. Ensuring PDMPs incorporate available overdose/naloxone deployment data, including the United States Department of Transportation's Emergency Medical Technician overdose database in a manner that complies with all relevant privacy and security laws and rules.

7. Increasing electronic prescribing to prevent diversion or forgery.

8. Educating dispensers on appropriate opioid dispensing.

## G. PREVENT MISUSE OF OPIOIDS

Support efforts to discourage or prevent misuse of opioids through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the following:

1. Funding media campaigns to prevent opioid misuse.

2. Corrective advertising or affirmative public education campaigns based on evidence.

3. Public education relating to drug disposal.

4. Drug take-back disposal or destruction programs.

5. Funding community anti-drug coalitions that engage in drug prevention efforts.

6. Supporting community coalitions in implementing evidence-informed prevention, such as reduced social access and physical access, stigma reduction—including staffing, educational campaigns, support for people in treatment or recovery, or training of coalitions in evidence-informed implementation, including the Strategic Prevention Framework developed by the U.S. Substance Abuse and Mental Health Services Administration ("*SAMHSA*").

7. Engaging non-profits and faith-based communities as systems to support prevention.

8. Funding evidence-based prevention programs in schools or evidence-informed school and community education programs and campaigns for students, families, school employees, school athletic programs, parent-teacher and student associations, and others.

9. School-based or youth-focused programs or strategies that have demonstrated effectiveness in preventing drug misuse and seem likely to be effective in preventing the uptake and use of opioids.

10. Create or support community-based education or intervention services for families, youth, and adolescents at risk for OUD and any co-occurring SUD/MH conditions.

11. Support evidence-informed programs or curricula to address mental health needs of young people who may be at risk of misusing opioids or other drugs, including emotional modulation and resilience skills.

12. Support greater access to mental health services and supports for young people, including services and supports provided by school nurses, behavioral health workers or other school staff, to address mental health needs in young people that (when not properly addressed) increase the risk of opioid or another drug misuse.

## H. PREVENT OVERDOSE DEATHS AND OTHER HARMS (HARM REDUCTION)

Support efforts to prevent or reduce overdose deaths or other opioid-related harms through evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the following:

1. Increased availability and distribution of naloxone and other drugs that treat overdoses for first responders, overdose patients, individuals with OUD and their friends and family members, schools, community navigators and outreach workers, persons being released from jail or prison, or other members of the general public.

2. Public health entities providing free naloxone to anyone in the community.

3. Training and education regarding naloxone and other drugs that treat overdoses for first responders, overdose patients, patients taking opioids, families, schools, community support groups, and other members of the general public.

4. Enabling school nurses and other school staff to respond to opioid overdoses, and provide them with naloxone, training, and support.

5. Expanding, improving, or developing data tracking software and applications for overdoses/naloxone revivals.

6. Public education relating to emergency responses to overdoses.

7. Public education relating to immunity and Good Samaritan laws.

8. Educating first responders regarding the existence and operation of immunity and Good Samaritan laws.

9. Syringe service programs and other evidence-informed programs to reduce harms associated with intravenous drug use, including supplies, staffing, space, peer support services, referrals to treatment, fentanyl checking, connections to care, and the full range of harm reduction and treatment services provided by these programs.

10. Expanding access to testing and treatment for infectious diseases such as HIV and Hepatitis C resulting from intravenous opioid use.

11. Supporting mobile units that offer or provide referrals to harm reduction services, treatment, recovery supports, health care, or other appropriate services to persons that use opioids or persons with OUD and any co-occurring SUD/MH conditions.

12. Providing training in harm reduction strategies to health care providers, students, peer recovery coaches, recovery outreach specialists, or other professionals that provide care to persons who use opioids or persons with OUD and any co-occurring SUD/MH conditions.

13. Supporting screening for fentanyl in routine clinical toxicology testing.

## PART THREE: OTHER STRATEGIES

### I. FIRST RESPONDERS

In addition to items in section C, D and H relating to first responders, support the following:

1. Education of law enforcement or other first responders regarding appropriate practices and precautions when dealing with fentanyl or other drugs.

2. Provision of wellness and support services for first responders and others who experience secondary trauma associated with opioid-related emergency events.

### J. LEADERSHIP, PLANNING AND COORDINATION

Support efforts to provide leadership, planning, coordination, facilitations, training and technical assistance to abate the opioid epidemic through activities, programs, or strategies that may include, but are not limited to, the following:

1. Statewide, regional, local or community regional planning to identify root causes of addiction and overdose, goals for reducing harms related to the opioid epidemic, and areas and populations with the greatest needs for treatment

intervention services, and to support training and technical assistance and other strategies to abate the opioid epidemic described in this opioid abatement strategy list.

2. A dashboard to (a) share reports, recommendations, or plans to spend opioid settlement funds; (b) to show how opioid settlement funds have been spent; (c) to report program or strategy outcomes; or (d) to track, share or visualize key opioid- or health-related indicators and supports as identified through collaborative statewide, regional, local or community processes.

3. Invest in infrastructure or staffing at government or not-for-profit agencies to support collaborative, cross-system coordination with the purpose of preventing overprescribing, opioid misuse, or opioid overdoses, treating those with OUD and any co-occurring SUD/MH conditions, supporting them in treatment or recovery, connecting them to care, or implementing other strategies to abate the opioid epidemic described in this opioid abatement strategy list.

4. Provide resources to staff government oversight and management of opioid abatement programs.

## K. TRAINING

In addition to the training referred to throughout this document, support training to abate the opioid epidemic through activities, programs, or strategies that may include, but are not limited to, those that:

1. Provide funding for staff training or networking programs and services to improve the capability of government, community, and not-for-profit entities to abate the opioid crisis.

2. Support infrastructure and staffing for collaborative cross-system coordination to prevent opioid misuse, prevent overdoses, and treat those with OUD and any co-occurring SUD/MH conditions, or implement other strategies to abate the opioid epidemic described in this opioid abatement strategy list (*e.g.*, health care, primary care, pharmacies, PDMPs, etc.).

## L. RESEARCH

Support opioid abatement research that may include, but is not limited to, the following:

1. Monitoring, surveillance, data collection and evaluation of programs and strategies described in this opioid abatement strategy list.

2. Research non-opioid treatment of chronic pain.

3. Research on improved service delivery for modalities such as SBIRT that demonstrate promising but mixed results in populations vulnerable to opioid use disorders.

4. Research on novel harm reduction and prevention efforts such as the provision of fentanyl test strips.

5. Research on innovative supply-side enforcement efforts such as improved detection of mail-based delivery of synthetic opioids.

6. Expanded research on swift/certain/fair models to reduce and deter opioid misuse within criminal justice populations that build upon promising approaches used to address other substances (*e.g.*, Hawaii HOPE and Dakota 24/7).

7. Epidemiological surveillance of OUD-related behaviors in critical populations, including individuals entering the criminal justice system, including, but not limited to approaches modeled on the Arrestee Drug Abuse Monitoring ("*ADAM*") system.

8. Qualitative and quantitative research regarding public health risks and harm reduction opportunities within illicit drug markets, including surveys of market participants who sell or distribute illicit opioids.

9. Geospatial analysis of access barriers to MAT and their association with treatment engagement and treatment outcomes.

# Exhibit D

# Subdivision Teva and Allergan Settlements Participation Form

**EXHIBIT D**

**Subdivision Teva and Allergan Settlements Participation Form**

| Governmental Entity: | State: |
|---|---|
| Authorized Official: | |
| Address 1: | |
| Address 2: | |
| City, State, Zip: | |
| Phone: | |
| Email: | |

The governmental entity identified above ("*Governmental Entity*"), in order to obtain and in consideration for the benefits provided to the Governmental Entity pursuant to the Settlement Agreements with Teva and Allergan ("*Teva and Allergan Settlements*"), and acting through the undersigned authorized official, hereby elects to participate in the Teva and Allergan Settlements, release all Released Claims against all Released Entities, and agrees as follows.

1. The Governmental Entity is aware of and has reviewed the Teva and Allergan Settlements, understands that all terms in this Participation Form have the meanings defined therein, and agrees that by signing this Participation Form, the Governmental Entity elects to participate in the Teva and Allergan Settlements and become a Participating Subdivision as provided therein.

2. The Governmental Entity shall, within 14 days of the execution of this Participation Form, secure the dismissal with prejudice of any Released Claims that it has filed.

3. The Governmental Entity agrees to the terms of the Teva and Allergan Settlements pertaining to Subdivisions as defined therein.

4. By agreeing to the terms of the Teva and Allergan Settlements and becoming a Releasor, the Governmental Entity is entitled to the benefits provided therein, including, if applicable, monetary payments beginning after the effective date.

5. The Governmental Entity agrees to use any monies it receives through the Teva and Allergan Settlements solely for the purposes provided therein.

6. The Governmental Entity submits to the jurisdiction of the Providence County Superior Court in the State of Rhode Island for resolving disputes to the extent provided in the Teva and Allergan Settlements.

7. The Governmental Entity has the right to enforce the Teva and Allergan Settlements as provided therein.

8. The Governmental Entity, as a Participating Subdivision, hereby becomes a Releasor for all purposes in the Teva and Allergan Settlements, and along with all departments, agencies, divisions, boards, commissions, districts, instrumentalities of any kind and attorneys, and any person in their official capacity elected or appointed to serve any of

the foregoing and any agency, person, or other entity claiming by or through any of the foregoing, and any other entity identified in the definition of Releasor, provides for a release to the fullest extent of its authority. As a Releasor, the Governmental Entity hereby absolutely, unconditionally, and irrevocably covenants not to bring, file, or claim, or to cause, assist or permit to be brought, filed, or claimed, or to otherwise seek to establish liability for any Released Claims against any Released Entity in any forum whatsoever. The releases provided for in the Teva and Allergan Settlements are intended by the Parties to be broad and shall be interpreted so as to give the Released Entities the broadest possible bar against any liability relating in any way to Released Claims and extend to the full extent of the power of the Governmental Entity to release claims. The Teva and Allergan Settlements shall be a complete bar to any Released Claim.

9. The Governmental Entity hereby takes on all rights and obligations of a Participating Subdivision as set forth in the Teva and Allergan Settlements.

10. In connection with the releases provided for in the Teva and Allergan Settlements, each Governmental Entity expressly waives, releases, and forever discharges any and all provisions, rights, and benefits conferred by any law of any state or territory of the United States or other jurisdiction, or principle of common law, which is similar, comparable, or equivalent to § 1542 of the California Civil Code, which reads:

> **General Release; extent.** A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, and that if known by him or her would have materially affected his or her settlement with the debtor or released party.

A Releasor may hereafter discover facts other than or different from those which it knows, believes, or assumes to be true with respect to the Released Claims, but each Governmental Entity hereby expressly waives and fully, finally, and forever settles, releases and discharges, upon the Effective Date, any and all Released Claims that may exist as of such date but which Releasors do not know or suspect to exist, whether through ignorance, oversight, error, negligence or through no fault whatsoever, and which, if known, would materially affect the Governmental Entities' decision to participate in the Teva and Allergan Settlements.

11. Nothing herein is intended to modify in any way the terms of the Teva and Allergan Settlements, to which Governmental Entity hereby agrees. To the extent this Participation Form is interpreted differently from the Teva and Allergan Settlements in any respect, the Teva and Allergan Settlement controls.

12. This Participation Form is conditioned on the Governmental Entity identified above entering into the *First Amendment To the Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds* which governs the allocation of the opioid settlement funds made under the Teva and Allergan

Settlements ("*Teva and Allergan Allocation Agreement*"). The *First Amendment To Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds* is specific to and only pertains to the Teva and Allergan Settlement. The effective date of this Participation Form shall be the date on which the State and the Governmental Entity identified above enter into a Teva and Allergan Allocation Agreement. In the event that the State does not enter into a Teva and Allergan Allocation Agreement with the Governmental Entity identified above, this Participation Form shall be null and void and shall confer no rights or obligations on the State of Rhode Island, the Released Entities, or the Governmental Entity.

I have all necessary power and authorization to execute this Participation Form on behalf of the Governmental Entity.

Signature: _____

Name: _____

Title: _____

Date: _____

# Exhibit E

# Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds

# RHODE ISLAND MEMORANDUM OF UNDERSTANDING BETWEEN THE STATE AND CITIES AND TOWNS RECEIVING OPIOID SETTLEMENT FUNDS

Whereas, the people of the State of Rhode Island and its communities have been harmed by the opioid epidemic, which was caused, in part, by manufacturers and distributors of opioids, and dispensers of opioids and related drugs (collectively, "Opioids Defendants"); and

Whereas, the actions of the Opioids Defendants have resulted in a rise in opioid addiction, overdoses, and deaths in Rhode Island, as well as increased healthcare, social services, and criminal justice costs and the destabilization of families and communities across the state; and

Whereas, the State and certain Rhode Island cities and towns are engaged in litigation seeking to hold certain Opioids Defendants accountable for the damage they have caused; and

Whereas, the State and the Eligible Cities and Towns share a common desire to abate and alleviate the impacts of the Opioids Defendants' misconduct through the State of Rhode Island in a coordinated and expeditious manner; and

Whereas, upon satisfaction of the terms of each of the Settlement Agreements, each will become binding on all Settling States and Participating Cities and Towns, and other settling entities party thereto;

Whereas, each Settlement Agreement encourages or allows each Settling State and its respective cities and towns to enter into a State-Subdivision Agreement, or a similar framework, in order to direct allocation of their portion of the Opioid Settlement Funds.

Now, therefore, the State and its Participating Cities and Towns enter into this Agreement (the "Agreement") relating to the allocation and use of the proceeds of the Settlement Agreements:

## I. Definitions

As used in this Agreement:

A. "Approved Purposes" means care, treatment, and other programs and expenditures designed to (1) address the misuse and abuse of opioid products; (2) treat or mitigate opioid use or related disorders; or (3) mitigate other alleged effects of, including on those injured as a result of, the opioid epidemic as identified by the terms of Exhibit C of the Distributor Settlement Agreement, Exhibit E of the Janssen Settlement Agreement, or any other relevant Settlement Agreement. For purposes of any payments pursuant to a Confirmation Order in a bankruptcy proceeding, the Approved Purposes means those approved by the confirmed plan. Qualifying expenditures may include reasonable related administrative expenses.

B. "Attorney General," "Chief Justice of the Rhode Island Supreme Court," "Director of the Department of Behavioral Healthcare, Developmental Disabilities & Hospitals," "Director of the Department of Health," "Governor," "Senate President," and "Speaker of the House," mean the officials holding these offices under Rhode Island law.

C. "Distributor Settlement Agreement" means an agreement between McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal"), and AmerisourceBergen Corporation ("Amerisource"), on the one hand, and the State of Rhode Island and Participating Subdivisions as that term is defined therein, on the other hand, to resolve opioid related claims against McKesson, Cardinal, and/or Amerisource.

D. "Eligible City or Town" means the cities or towns of Barrington, Bristol, Burrillville, Central Falls, Charlestown, Coventry, Cranston, Cumberland, East Greenwich, East Providence, Exeter, Foster, Glocester, Hopkinton, Jamestown, Johnston, Lincoln, Little Compton, Middletown, Narragansett, New Shoreham, Newport, North Kingstown, North Providence, North Smithfield, Pawtucket, Portsmouth, Providence, Richmond, Scituate, Smithfield, South Kingstown, Tiverton, Warren, Warwick, West Greenwich, West Warwick, Westerly, and Woonsocket. Together the Eligible Cities or Towns are the "Eligible Cities and Towns."

E. "EOHHS" means the Rhode Island Executive Office of Health and Human Services, or successor agency, and "Secretary" means the Secretary of EOHHS, or successor official.

F. "Janssen Settlement Agreement" means that certain settlement agreement dated as of July 21, 2021 setting forth the terms of settlement between and among Janssen Pharmaceuticals, Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc., on the one hand, and certain Settling States and Participating Subdivisions on the other hand.

G. "Opioid Settlement Funds" means all the funds deposited into a Rhode Island Settlement Fund or sub-fund, deposited into a Rhode Island Qualified Settlement Fund, or held and distributed by an administrator or a Rhode Island Qualified Settlement Administrator pursuant to the terms of the relevant Settlement Agreements, except for any funds needed to pay an administrator or a Rhode Island Qualified Settlement Administrator, or designated by a Settlement Agreement or court order for State or Participating Subdivision attorneys' fees and costs.

H. "Participating City or Town" means an Eligible City or Town that is both (i) a signatory to this Agreement and (ii) an Initial Participating Subdivision as defined in each Settlement Agreement. Together the Participating Cities or Towns are the "Participating Cities and Towns."

I. "Parties" means the State and each Eligible City or Town that is a signatory to this Agreement.

J. "Settlement Agreements" means the Distributor Settlement Agreement, the Janssen Settlement agreement, and any similar agreement (including consent judgments or consent decrees) entered into after the date of this Agreement, by between, or among one or more opioid manufacturers, pharmaceutical distributors, or pharmacies, or an affiliate, agent, consultant, or advisor of an opioid manufacturer, if mutually agreed to by the Parties in writing. "Settlement Agreement" means one such agreement.

In addition to the foregoing, upon confirmation of the plan in any bankruptcy proceeding for which the State will receive a payment or distribution in connection with claims similar to those released in the Settlement Agreements, which shall include both *In re Purdue Pharma L.P., et al*, No-19-23649 (RDD) (Bankr. S.D. N.Y.) and *In re: Mallinckrodt PLC, et al.*, No. 20-12522 (JTD) (Bankr. D. Del.), such confirmed plan will also become a Settlement Agreement hereunder.

K. "State" means the State of Rhode Island acting through its Attorney General.

Capitalized terms used and not otherwise defined herein have the meaning given to them in the Settlement Agreements.

**II. Allocation of Settlement Proceeds**

A. *Allocation.* All Opioid Settlement Funds, at the times designated in the Settlement Agreements, shall be divided and distributed as follows:

1. 20% directly to the Participating Cities and Towns ("City and Town Share") for Approved Purposes in accordance with Section III below.

2. 80% directly to the State ("Statewide Abatement Share") for forward-looking Approved Purposes throughout the state, which share shall be held in the Rhode Island Statewide Opioid Abatement Account in accordance with Sections IV and V below.

B. *Use of Funds.* All Opioid Settlement Funds, regardless of allocation, shall be utilized solely for Approved Purposes to abate the harms of the opioid epidemic.

**III. City and Town Share**

A. *Allocation and Payment.* The division of the City and Town Share paid to Participating Cities and Towns shall be based on the allocation set forth in Exhibit A, which assigns each Eligible City or Town a percentage share of funds.

B. *Use of Funds.* The City and Town Share shall be used for Approved Purposes and the Parties intend for the Opioid Settlement Funds to be used on forward-looking opioid abatement efforts. But, the City and Town Share may also be used for past expenditures so long as the expenditures were made for Approved Purposes and are not otherwise restricted by a confirmed plan in a bankruptcy proceeding. Prior to using any portion of the City and Town Share as restitution for past expenditures, a Participating City or Town

shall pass a resolution or take equivalent governmental action that explains its determination that its prior expenditures for Approved Purposes are greater than or equal to the amount of the City and Town Share that the City or Town seeks to use for restitution.

C. *Collaborative Abatement Initiatives Encouraged.* Participating Cities and Towns may, and are encouraged to, share, pool, or collaborate on opioid abatement efforts with their respective allocation of the City and Town Share in any manner they choose, so long as the shared, pooled, or collaborative abatement efforts comply with the terms of this Agreement and the Settlement Agreements.

D. *Option to Direct Allocation to Statewide Abatement.* Participating Cities and Towns may, at their discretion, forego their allocation of the City and Town Share and direct their allocation to the Statewide Abatement Share by affirmatively notifying the Advisory Committee and any relevant settlement fund administrator on an annual basis of their decision to forego their allocation of the City and Town Share and designation to the Statewide Abatement Share.

E. *Non-participating City or Town.* In the event an Eligible City or Town does not participate in the Settlement Agreements, the allocation percentage for that Eligible City or Town shall be redistributed to the Participating Cities and Towns based on a recalculated allocation that does not include the non-participating city or town.

F. *Municipal Merger or Dissolution.* In the event an Eligible City or Town merges, dissolves, or ceases to exist, the allocation percentage for that City or Town shall be redistributed equitably based on the composition of the successor City or Town.

G. *City and Town Attorneys' Fees.* The Parties agree that attorneys representing the Participating Cities and Towns in litigation against the Opioids Defendants will satisfy any contractual obligations relating to those legal representations through the mechanisms provided for in the Settlement Agreements. Notwithstanding the provisions of part B of this subsection, no portion of the City and Town Share shall be used to pay any attorneys' fees, costs, or other contractual obligations relating to legal representation in litigation against the Opioids Defendants.

## IV. Statewide Abatement Share

A. *Allocation and Payment.* The Statewide Abatement Share will be paid directly to the State and these funds shall be held in an account, the Rhode Island Statewide Opioid Abatement Account (the "R.I. Statewide Opioid Abatement Account"), that (1) is established by, authorized by, or subject to any court orders or consent judgments entered to effectuate the terms of the Settlement Agreements including in *State of Rhode Island v. Purdue Pharma L.P. et al.*, C.A. No. PC-2018-4555; (2) has the restricted purpose of holding these funds separately, ensuring they are not comingled with non-Opioid Settlement Funds, and distributing the funds for Approved Purposes; and (3) otherwise meets any requirements for such a fund or account in the Settlement Agreements. The Parties intend for the R.I. Statewide Opioid Abatement Account to hold and distribute the

Statewide Abatement Share in a manner substantially similar to the Opioid Stewardship Fund created under Chapter 28.10 of Title 21 of the Rhode Island General Laws and agree that the R.I. Statewide Opioid Abatement Account may be similarly codified into law by the General Assembly.

B. *Use of Funds.*

1. The Statewide Abatement Share shall be used for forward-looking Approved Purposes only.

2. Consistent with the provisions of Section V of this Agreement and Section 15 of Article IX of the Rhode Island Constitution, at least annually the Secretary shall present to the Governor, for inclusion in the Governor's budget presentation to the General Assembly, the Secretary's recommendations on the use of the Statewide Abatement Share.

C. *Reporting.* The Secretary shall report to the Advisory Committee annually on the distribution and use of funds from the Statewide Abatement Share.

D. *Compliance.* Recipients of funds distributed from the Statewide Abatement Share shall be subject to auditing and other compliance procedures as deemed appropriate by the Secretary.

## V. Advisory Committee

A. *Committee Established.* An Advisory Committee (the "Advisory Committee"), consisting of the representatives in part B of this subsection, shall be created to ensure that the State and the Participating Cities and Towns have equal input into the distribution of the Statewide Abatement Share for Approved Purposes across the state of Rhode Island.

B. *Representatives.* The Advisory Committee shall consist of the following seventeen (17) members:

1. *State Representatives.* Six (6) State representatives as follows:

a) Attorney General or designee;

b) Speaker of the House or designee;

c) Senate President or designee;

d) Chief Justice of the Rhode Island Supreme Court or designee;

e) Director of the Rhode Island Department of Health ("RIDOH"); and

f) Director of the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities & Hospitals ("BHDDH").

2. *Participating City and Town Representatives.* Six (6) Participating City and Town representatives as follows:

    a) Mayor of the City of Providence or designee;

    b) Representative from a city or town in Bristol County;

    c) Representative from a city or town in Kent County;

    d) Representative from a city or town in Newport County;

    e) Representative from a city or town in Providence County other than the City of Providence; and

    f) Representative from a city or town in Washington County (together with the Representatives from a city or town in Bristol, Kent, Newport, and Providence Counties are the "County Representatives").

    Participating Cities and Towns from Bristol, Kent, Newport, Providence, and Washington counties shall collaborate to appoint the County Representatives. The County Representatives shall serve three (3) year terms.

3. *Expert Representatives.* Three (3) experts ("Expert Representatives") drawn from fields including but not limited to: public health, pharmacology, epidemiology, emergency medicine, behavioral health, and recovery. The Expert Representatives shall be appointed by a majority vote of the State Representatives and the Participating City and Town Representatives. To stagger the Expert Representative terms, the initial Expert Representative appointments shall be for two (2) years, three (3) years, and four (4) years, and all subsequent Expert Representative appointments shall be for three (3) year terms.

4. *Community Representatives.* Two (2) Community Representatives ("Community Representatives"). The Community Representatives shall be appointed by a majority vote of the State Representatives and the Participating City and Town Representatives. To stagger the Community Representative terms, the initial Community Representative appointments shall be for two (2) years, and three (3) years, and all subsequent Community Representative appointments shall be for two (2) year terms.

C. *Chair.* The Advisory Committee shall be chaired by a non-voting representative appointed by the Governor.

D. *Administrative and Technical Support.* EOHHS shall provide staff support to the Advisory Committee and assist the Advisory Committee in the fulfillment of its responsibilities under this Agreement.

E. *Meetings and Process for Receiving Public and Local Government Input.*

1. The Advisory Committee shall meet at least quarterly.

2. Meetings of the Advisory Committee shall be public, open meetings consistent with the Open Meetings Act, Chapter 46 of Title 42 of the Rhode Island General Laws.

3. The Advisory Committee shall, in consultation with EOHHS, establish a process for receiving input from Rhode Island's communities, provider organizations, and cities and towns regarding how the opioid crisis is affecting their communities, understanding their abatement needs, and considering proposals for opioid abatement strategies and responses.

   The Advisory Committee is encouraged to further coordinate with established groups like the Governor's Overdose Prevention and Intervention Task Force, as well as organizations focusing on prevention, rescue, harm reduction, treatment, and recovery strategies, to gather community input, understand abatement needs, and consider proposals for opioid abatement strategies and responses.

F. *Recommendations.*

1. *Statewide Abatement Recommendations.* The Advisory Committee shall, at least annually, make formal recommendations to the Secretary on the use of the Statewide Abatement Share (the "Statewide Abatement Recommendations"). To aid the Advisory Committee in formulating the Statewide Abatement Recommendations, EOHHS, RIDOH, and BHDDH shall present information regarding the State's opioid abatement strategy and appropriations plan, and information on how that strategy responds to the opioids crisis and the abatement needs of Rhode Island's communities. The Advisory Committee may also consider how non-Opioid Settlement Funds are used as part of the State's opioid abatement strategy when formulating the Statewide Abatement Recommendations.

2. *Good Faith Review and Consideration by Secretary.* The Secretary shall review and consider the Statewide Abatement Recommendations and shall make a good faith effort to incorporate the Statewide Abatement Recommendations into EOHHS's annual budget process.

3. *Deviation from Statewide Abatement Recommendations.* If the Secretary substantially deviates from the Statewide Abatement Recommendations, the Secretary shall provide the Advisory Committee with a written explanation, that will be made public, of any substantial deviations.

## VI. General Terms

A. *Relationship of this Agreement to Other Agreements and Resolutions.* The Parties acknowledge and agree the Distributor Settlement Agreement and the Janssen Settlement Agreement will require Participating Cities and Towns to release all their claims against the settling defendants to receive Opioid Settlement Funds. The Parties further acknowledge and agree based on the terms of the Distributor Settlement Agreement and

the Janssen Settlement Agreement that a Participating City or Town may receive funds pursuant to this Agreement only after complying with all the requirements set forth in the Distributor Settlement Agreement and the Janssen Settlement Agreement to release the city or town's claims. If another Settlement Agreement contains similar requirements, the Parties acknowledge that a Participating City or Town may receive funds pursuant to that agreement only after complying with all the requirements set forth in that agreement to release the city or town's claims.

B. *Scope of this Agreement.* The Parties acknowledge and agree that they must comply with all the requirements of the Settlement Agreements and that this Agreement does not excuse any requirements placed upon them by the terms of the Settlement Agreements, except to the extent those terms allow for a State-Subdivision Agreement or Statewide Abatement Agreement to do so.

C. *Legislation.* The Parties may seek to further codify the terms of this Agreement in the Rhode Island General Laws through legislation that may be submitted to the General Assembly.

D. *Applicable Law, Venue, and Severability.* Unless required otherwise by a Settlement Agreement, this Agreement shall be interpreted using Rhode Island law and any action related to the provisions of this Agreement must be adjudicated by the Superior Court of Providence County. If any provision of this Agreement is held invalid by a court of competent jurisdiction, this invalidity does not affect any other provision which can be given effect without the invalid provision.

E. *Counterparts.* This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.

## VII. Amendments

A. *Amendments as Necessary.* The Parties agree to make such amendments as necessary to implement the intent of this Agreement.

B. *Written Amendments.* This Agreement may be amended by written agreement of the Parties.

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: 1/21/2022

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

By:
Title: Date: _____

SIGNATURE PAGES

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: James J. Cunha Date: 12/21/2021
Town Manager
Barrington, RI

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

By:
Title: Date: _____

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By: Michael A Ursillo
Title: Town Solicitor Date: 1/5/21

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

By:
Title: Date: _____

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**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

Michael C. Wood

By: Michael C. Wood
Title: MANAGER Date: 12/31/2021

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

By:
Title: Date: _____

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

Maria Rivera
By: Maria Rivera
Title: Mayor Date: 10/29/21

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

By:
Title: Date: _____

SIGNATURE PAGES

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By: Deborah Carney
Title: Council President Date: 01-05-22

**TOWN OF COVENTRY**

By:
Title: Date: _____

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

Peter F. Neronha
Attorney General Date: _____

The Participating Cities and Towns:

**TOWN OF BARRINGTON**

By:
Title: Date: _____

**TOWN OF BRISTOL**

By:
Title: Date: _____

**TOWN OF BURRILLVILLE**

By:
Title: Date: _____

**CITY OF CENTRAL FALLS**

By:
Title: Date: _____

**TOWN OF CHARLESTOWN**

By:
Title: Date: _____

**TOWN OF COVENTRY**

Ann Dickson

By:
Title: Date: Jan 3 2022

Coventry town Council
PRESIDENT

SIGNATURE PAGES

**CITY OF CRANSTON**

By:
Title: Solicitor Date: 12/29/21

**TOWN OF CUMBERLAND**

By:
Title: Date: _____

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

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Title: Date: _____

**TOWN OF HOPKINTON**

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Title: Date: _____

**TOWN OF JAMESTOWN**

By:
Title: Date: _____

**TOWN OF JOHNSTON**

By:
Title: Date: _____

**CITY OF CRANSTON**

By:
Title: Date: _____

**TOWN OF CUMBERLAND**

By: Jeffrey J Mutter
Title: MAYOR Date: 12/29/2021

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

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Title: Date: _____

**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

By:
Title: Date: _____

**TOWN OF JOHNSTON**

By:
Title: Date: _____

**CITY OF CRANSTON**

By:
Title: Date: _____

**TOWN OF CUMBERLAND**

By:
Title: Date: _____

**TOWN OF EAST GREENWICH**

By: Andrew E. Nota
Title: Town Manager Date: 12/28/2021

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

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**TOWN OF JAMESTOWN**

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Title: Date: _____

**TOWN OF JOHNSTON**

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Title: Date: _____

**CITY OF CRANSTON**

By:
Title: Date: _____

**TOWN OF CUMBERLAND**

By:
Title: Date: _____

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By: ROBERTO DASILVA
Title: MAYOR Date: 1/4/2022

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

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**TOWN OF JAMESTOWN**

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**TOWN OF JOHNSTON**

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Title: Date: _____

**CITY OF CRANSTON**

By:
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**TOWN OF CUMBERLAND**

By:
Title: Date: _____

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By: Daniel W Patterson
Title: Council President Date: 1-3-2023

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

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**TOWN OF JOHNSTON**

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**CITY OF CRANSTON**

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**TOWN OF CUMBERLAND**

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Title: Date: _____

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By: Denise L. DiFrango
Title: Town Council President Date: 12/31/21

**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

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Title: Date: _____

**TOWN OF JOHNSTON**

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Title: Date: _____

**CITY OF CRANSTON**

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**TOWN OF CUMBERLAND**

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Title: Date: _____

**TOWN OF EAST GREENWICH**

By:
Title: Date: _____

**CITY OF EAST PROVIDENCE**

By:
Title: Date: _____

**TOWN OF EXETER**

By:
Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

William E Dunlett

By: Title: Vice President Date: 12-29-21

**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

By:
Title: Date: _____

**TOWN OF JOHNSTON**

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Title: Date: _____

**CITY OF CRANSTON**

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**TOWN OF CUMBERLAND**

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**TOWN OF EAST GREENWICH**

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**CITY OF EAST PROVIDENCE**

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**TOWN OF EXETER**

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Title: Date: _____

**TOWN OF FOSTER**

By:
Title: Date: _____

**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

By: Brian Russo
Title: Town Manager Date: 12/27/21

**TOWN OF JAMESTOWN**

By:
Title: Date: _____

**TOWN OF JOHNSTON**

By:
Title: Date: _____

**CITY OF CRANSTON**

By:
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**TOWN OF CUMBERLAND**

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**TOWN OF EAST GREENWICH**

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**CITY OF EAST PROVIDENCE**

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**TOWN OF FOSTER**

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**TOWN OF GLOCESTER**

By:
Title: Date: _____

**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

By: Jamie A. Hainsworth
Title: Town Admin. Date: 1/5/2022

**TOWN OF JOHNSTON**

By:
Title: Date: _____

**CITY OF CRANSTON**

By:
Title: Date: _____

**TOWN OF CUMBERLAND**

By:
Title: Date: _____

**TOWN OF EAST GREENWICH**

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**CITY OF EAST PROVIDENCE**

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**TOWN OF EXETER**

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**TOWN OF FOSTER**

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**TOWN OF GLOCESTER**

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**TOWN OF HOPKINTON**

By:
Title: Date: _____

**TOWN OF JAMESTOWN**

By:
Title: Date: _____

**TOWN OF JOHNSTON**

By: Marion Joseph M. Polisena
Title: Mayor Town of Johnston Date: 1/11/2022

**TOWN OF LINCOLN**

By: Philip Gould
Title: Town Administrater Date: Dec/30/21

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

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Title: Date: _____

**CITY OF NEWPORT**

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**TOWN OF NORTH KINGSTOWN**

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**TOWN OF NORTH PROVIDENCE**

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**TOWN OF NORTH SMITHFIELD**

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**CITY OF PAWTUCKET**

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**TOWN OF LINCOLN**

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**TOWN OF LITTLE COMPTON**

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Title: Date: 1/14/22

**TOWN OF MIDDLETOWN**

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**TOWN OF NARRAGANSETT**

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**TOWN OF NEW SHOREHAM**

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**CITY OF NEWPORT**

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**TOWN OF NORTH KINGSTOWN**

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**TOWN OF NORTH PROVIDENCE**

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**TOWN OF NORTH SMITHFIELD**

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**CITY OF PAWTUCKET**

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**TOWN OF LINCOLN**

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**TOWN OF LITTLE COMPTON**

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**TOWN OF MIDDLETOWN**

By:
Title: Date: 1/18/21

**TOWN OF NARRAGANSETT**

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Title: Date: _____

**TOWN OF NEW SHOREHAM**

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Title: Date: _____

**CITY OF NEWPORT**

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**TOWN OF NORTH KINGSTOWN**

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**TOWN OF NORTH PROVIDENCE**

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**TOWN OF NORTH SMITHFIELD**

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**CITY OF PAWTUCKET**

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**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By: JAMES J. KELLY
Title: TOWN MANAGER Date: 1/4/22

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

Maryanne Crawford

By: Maryanne Crawford
Title: Town Manager Date: 12/30/2021

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By: Joseph J. Nicholson, Jr.
Title: City Manager Date: 12/30/21

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By: A. Ralph Mollis
Title: Town Manager Date: 12-27-2021

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By: Charles A. Lombardi
Title: MAYOR Date: 1/5/2022

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

By:
Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By: PAUL ZUWOLENSKI
Title: TOWN Administrator Date: 01/05/2022

**CITY OF PAWTUCKET**

By:
Title: Date: _____

**TOWN OF LINCOLN**

By:
Title: Date: _____

**TOWN OF LITTLE COMPTON**

By:
Title: Date: _____

**TOWN OF MIDDLETOWN**

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Title: Date: _____

**TOWN OF NARRAGANSETT**

By:
Title: Date: _____

**TOWN OF NEW SHOREHAM**

By:
Title: Date: _____

**CITY OF NEWPORT**

By:
Title: Date: _____

**TOWN OF NORTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF NORTH PROVIDENCE**

By:
Title: Date: _____

**TOWN OF NORTH SMITHFIELD**

By:
Title: Date: _____

**CITY OF PAWTUCKET**

By: Donald R Grebien
Title: MAYOR Date: 12/29/21

**TOWN OF PORTSMOUTH**

By: Kevin R. Gavin
Title: Town Solicitor Date: 12/24/2021

**CITY OF PROVIDENCE**

By:
Title: Date: _____

**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By: Jeff Dana
Title: City Solicitor Date: 12/22/21

**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By:
Title: Date: _____

**TOWN OF RICHMOND**

Karen Ellsworth

By: Karen R. Ellsworth
Title: Town Solicitor Date: 5 January 2022

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
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**TOWN OF WARREN**

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**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By:
Title: Date: _____

**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

Abbie Groves

By: Abbie Groves
Title: Town Council President Date: 12/30/21

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

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**CITY OF WARWICK**

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Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By:
Title: Date: _____

**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By: Randy R. Rossi
Title: Town Manager Date: 1/6/22

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By:
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**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

Theresa L. Murphy

By: Theresa L Murphy
Title: Town Manager Date: 12/24/2021

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
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**TOWN OF PORTSMOUTH**

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**CITY OF PROVIDENCE**

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**TOWN OF RICHMOND**

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**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

Michael J Marcello

By: Michael J Marcello #5221
Title: Solicitor Date: 12/27/2021

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

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**CITY OF PROVIDENCE**

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**TOWN OF RICHMOND**

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Title: Date: _____

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By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

Kate Michaud

By: Kate Michaud
Title: Town Manager Date: 12/24/21

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

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**TOWN OF RICHMOND**

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**TOWN OF WARREN**

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Title: Date: _____

**CITY OF WARWICK**

By: Michael A. Willo
Title: City Solicitor Date: 12/30/21

**TOWN OF WEST GREENWICH**

By:
Title: Date: _____

**TOWN OF PORTSMOUTH**

By:
Title: Date: _____

**CITY OF PROVIDENCE**

By:
Title: Date: _____

**TOWN OF RICHMOND**

By:
Title: Date: _____

**TOWN OF SCITUATE**

By:
Title: Date: _____

**TOWN OF SMITHFIELD**

By:
Title: Date: _____

**TOWN OF SOUTH KINGSTOWN**

By:
Title: Date: _____

**TOWN OF TIVERTON**

By:
Title: Date: _____

**TOWN OF WARREN**

By:
Title: Date: _____

**CITY OF WARWICK**

By:
Title: Date: _____

**TOWN OF WEST GREENWICH**

Kevin A. Breene

By: KEVIN A. BREENE
Title: TOWN ADMINISTRATOR Date: 12/27/21

**TOWN OF WEST WARWICK**

By: Mark A. Knott
Title: Town Manager Date: 12/20/2021

**TOWN OF WESTERLY**

By:
Title: Date: _____

**CITY OF WOONSOCKET**

By:
Title: Date: _____

**TOWN OF WEST WARWICK**

By:
Title: Date:

**TOWN OF WESTERLY**

SHAWN LACEY

By:
Title: TOWN MANAGER Date: 1/10/2022

**CITY OF WOONSOCKET**

By:
Title: Date:

**TOWN OF WEST WARWICK**

By:
Title: Date: _____

**TOWN OF WESTERLY**

By:
Title: Date: _____

**CITY OF WOONSOCKET**

By: John J. DeSimone
Title: City Solicitor Date: 11/2/22

SIGNATURE PAGES

**EXHIBIT A**
**CITY AND TOWN SHARE ALLOCATION**

| | |
|---|---|
| Barrington | 2.3000539202% |
| Bristol | 1.0821868960% |
| Burrillville | 1.3272036109% |
| Central Falls | 0.9147584689% |
| Charlestown | 0.5887860100% |
| Coventry | 3.5886939036% |
| Cranston | 7.8869595262% |
| Cumberland | 2.4742003754% |
| East Greenwich | 1.7467671439% |
| East Providence | 4.3247728580% |
| Exeter | 0.0071810640% |
| Foster | 0.2489021533% |
| Glocester | 0.8508469130% |
| Hopkinton | 0.7098006614% |
| Jamestown | 0.4220295287% |
| Johnston | 3.0898685140% |
| Lincoln | 2.1171973520% |
| Little Compton | 0.2663017745% |
| Middletown | 1.2877439601% |
| Narragansett | 1.2760123800% |
| New Shoreham | 0.2118269375% |
| Newport | 2.3339316695% |
| North Kingstown | 2.6500524514% |
| North Providence | 2.5306229398% |
| North Smithfield | 1.1299013506% |
| Pawtucket | 5.9652217345% |
| Portsmouth | 1.2807429020% |
| Providence | 21.4858080262% |
| Richmond | 0.0818789542% |
| Scituate | 1.0248588645% |
| Smithfield | 1.7724673574% |
| South Kingstown | 2.3282747894% |
| Tiverton | 0.9907730639% |
| Warren | 0.1394116029% |
| Warwick | 9.9418184427% |
| West Greenwich | 0.7104734659% |
| West Warwick | 3.0239943495% |
| Westerly | 2.0135754535% |
| Woonsocket | 3.8740986306% |

# Exhibit F

# Proposed First Amendment to Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds

**FIRST AMENDMENT TO RHODE ISLAND MEMORANDUM OF UNDERSTANDING BETWEEN THE STATE AND CITIES AND TOWNS RECEIVING OPIOID SETTLEMENT FUNDS**

The State of Rhode Island (the "State") and the Participating Cities and Towns entered into the Rhode Island Memorandum of Understanding Between the State and Cities and Towns Receiving Opioid Settlement Funds (the "R.I. MOU), which became effective on January 21, 2022, and governs the allocation and use of the proceeds of Settlement Agreements as that term is defined in the R.I. MOU. This First Amendment (the "First Amendment") modifies the R.I. MOU pursuant to Section VII of the agreement.

## I. Amendment to Cover Additional Settlement Agreements

The State and the Participating Cities and Towns agree to amend the R.I. MOU as follows:

A. The Teva Settlement Agreement and the Allergan Settlement Agreement (jointly the "Teva and Allergan Settlement Agreements") are Settlement Agreements under Section I.J of the R.I. MOU.

B. Section I, "Definitions" will be modified to add the following:

> "L. "Teva Settlement Agreement" means an agreement between Teva Pharmaceuticals Ltd., on the one hand, and the State of Rhode Island on the other hand, to resolve opioid related claims against Teva."
>
> "M. "Allergan Settlement Agreement" means an agreement between Allergan, on the one hand, and the State of Rhode Island on the other hand, to resolve opioid related claims against Allergan."
>
> "H. "Participating City or Town" means an Eligible City or Town that is both (i) a signatory to this Agreement and (ii) an Initial Participating Subdivision as defined in each Settlement Agreement~~.~~ and, for the purposes of the Teva and Allergan Settlement Agreements, is both (i) a signatory to the First Amendment and (ii) a Participating Subdivision as defined in those agreements. Together the Participating Cities or Towns are the "Participating Cities and Towns."

C. Section II., "Allocation of Settlement Proceeds" will be modified to add the following:

> "C. *Payment of City and Town Share of the Teva and Allergan Settlement Agreements.* For the City and Town Share of the Opioid Settlement Funds resulting from the Teva and Allergan Settlement Agreements:
>
> 1. If, within 60 days of the Effective Date of the Teva and Allergan Settlement Agreements, a sufficient number of Eligible Cities and Towns have become Participating Cities and Towns such that the population of the Participating Cities and Towns accounts for 95% or more of the population of all Eligible Cities and Towns,

each Participating City or Town that has joined by that date shall be paid an amount equal to the full amount of Opioid Settlement Funds the City or Town is due to receive over the duration of the Teva and Allergan Settlement Agreements, based on the allocation in Section III.A, within the first year of the Teva and Allergan Settlement Agreements. A Participating City or Town that receives such a lump-sum payment will not receive any further payments from the Teva and Allergan Settlement Agreements.

2. An Eligible City or Town that becomes a Participating City or Town after 60 days following the Effective Date of the Teva and Allergan Settlement Agreements, shall receive its share of Opioid Settlement Funds as determined under Section III.A at the times designated in those settlement agreements."

D. Section VI.A, "*Relationship of this Agreement to Other Agreements and Resolutions*" will be modified as follows, "The Parties acknowledge and agree the Distributor Settlement Agreement, ~~and~~ the Janssen Settlement Agreement, the Teva Settlement Agreement, and the Allergan Settlement Agreement will require Participating Cities and Towns to release all their claims against the settling defendants to receive Opioid Settlement Funds. The Parties further acknowledge and agree based on the terms of the Distributor Settlement Agreement, ~~and~~ the Janssen Settlement Agreement, and the Teva and Allergan Settlement Agreement that a Participating City or Town may receive funds pursuant to this Agreement only after complying with all the requirements set forth in the Distributor Settlement Agreement, ~~and~~ the Janssen Settlement Agreement, and the Teva and Allergan Settlement Agreement to release the city or town's claims. If another Settlement Agreement contains similar requirements, the Parties acknowledge that a Participating City or Town may receive funds pursuant to that agreement only after complying with all the requirements set forth in that agreement to release the city or town's claims."

## II. Related Terms

A. *Relationship of this Amendment to Other Provisions.* Except as amended in this First Amendment, all other provisions within the R.I. MOU shall remain in full force and effect.

B. *Counterparts.* This First Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement.

Accepted and agreed to by the undersigned:

**STATE OF RHODE ISLAND**

_____

Peter F. Neronha
Attorney General Date: _____

_____

CITY/TOWN

Signature: _____

By: _____

Title: _____ Date: _____

# Exhibit G
# Injunctive Relief

## EXHIBIT G

## Injunctive Relief

I. **Definitions Specific to this Exhibit**

A. "Cancer-Related Pain Care" means care that provides relief from pain resulting from a patient's active cancer or cancer treatment as distinguished from treatment provided during remission.

B. "End-of-Life Care" means care for persons with a terminal illness or at high risk for dying in the near future in hospice care, hospitals, long-term care settings, or at home.

C. "Downstream Customer Data" shall mean transaction information that Teva collects relating to its direct customers' sales to downstream customers, including chargeback data tied to Teva providing certain discounts, "867 data" and IQVIA data.

D. "Health Care Provider" shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services and/or prescribe pharmaceutical products and any medical facility, practice, hospital, clinic or pharmacy.

E. "Including but not limited to", when followed by a list or examples, shall mean that list or examples are illustrative instances only and shall not be read to be restrictive.

F. "In-Kind Support" shall mean payment or assistance in the form of goods, commodities, services, or anything else of value.

G. "Lobby" and "Lobbying" shall have the same meaning as "lobbying activities" and "lobbying contacts" under the federal lobbying disclosure act, 2 U.S.C. § 1602 *et seq.*, and any analogous state or local provisions governing the person or entity being lobbied in that particular state or locality. As used in this document, "Lobby" and "Lobbying" include Lobbying directly or indirectly, through grantees or Third Parties.

H. "Opioid(s)" shall mean all natural, semi-synthetic, or synthetic chemicals that interact with opioid receptors and act like opium. For the avoidance of doubt, the term Opioid shall not include the opioid antagonists naloxone or naltrexone.

I. "Opioid Product(s)" shall mean all current and future medications containing Opioids approved by the U.S. Food & Drug Administration ("FDA") and listed by the Drug Enforcement Administration ("DEA") as Schedule II, III, or IV pursuant to the federal Controlled Substances Act (including but not limited to

buprenorphine, codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, oxycodone, oxymorphone, tapentadol, and tramadol). The term "Opioid Products(s)" shall not include (i) methadone, buprenorphine, or other substances when used exclusively to treat opioid abuse, addiction, or overdose; or (ii) raw materials, immediate precursors, and/or active pharmaceutical ingredients ("APIs") used in the manufacture or study of Opioids or Opioid Products, but only when such materials, immediate precursors, and/or APIs are sold or marketed exclusively to DEA-licensed manufacturers or DEA-licensed researchers.

J. "OUD" shall mean opioid use disorder defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM–5)*, as updated or amended.

K. "Promote," "Promoting," "Promotion," and "Promotional" shall mean dissemination of information or other practices intended or reasonably anticipated to increase sales or prescriptions, or that attempts to influence prescribing practices of Health Care Providers in the United States.

L. "Qualified Researcher" shall mean any researcher holding a faculty appointment or research position at an institution of higher education, a research organization, a nonprofit organization, or a government agency.

M. "Suspicious Order" shall have the same meaning as provided by the Controlled Substances Act, 21 U.S.C. §§ 801-904, and the regulations promulgated thereunder and analogous Rhode Island state laws and regulations.

N. "Teva" means Teva Pharmaceuticals USA, Inc. ("Teva USA"); Cephalon, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Warner Chilcott Co., LLC; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories Inc.-Salt Lake City; and Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida.

O. "Third Party" shall mean any person or entity other than Teva or a government entity.

P. "Treatment of Pain" shall mean the provision of therapeutic modalities to alleviate or reduce pain.

Q. "Unbranded Information" shall mean any information that does not identify a specific branded or generic product(s).

II. **Injunctive Relief**

A. General Provisions

1. Teva shall not make any written or oral statement about Opioids or any Opioid Product that is false, misleading, and/or deceptive as defined under the law of Rhode Island.

2. Teva shall not represent that Opioids or any Opioid Products have approvals, characteristics, uses, benefits, or qualities that they do not have.

B. Ban on Promotion

1. Teva shall not engage in the Promotion of Opioids or Opioid Products including, but not limited to, by:

a. Employing or contracting with sales representatives or other persons to Promote Opioids or Opioid Products to Health Care Providers, patients, or persons involved in determining the Opioid Products included in formularies;

b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events for Promotion of Opioids or Opioid Products;

c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs relating to Opioids or Opioid Products;

d. Creating, sponsoring, operating, controlling, or otherwise providing financial support or In-Kind Support to any website, network, and/or social or other media account for the Promotion of Opioids or Opioid Products;

e. Creating, sponsoring, distributing, or otherwise providing financial support or In-Kind Support for materials Promoting Opioids or Opioid Products, including but not limited to brochures, newsletters, pamphlets, journals, books, and guides;

f. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote Opioids or Opioid Products, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements; or

g. Engaging in Internet search engine optimization or other techniques designed to Promote Opioids or Opioid Products by improving rankings or making content appear among the top results in an Internet search or otherwise be more visible or more accessible to the public on the Internet.

2. Notwithstanding subsection II.B.1 directly above, Teva may:

a. Maintain a corporate website;

b. Maintain a website that contains principally the following content for any Opioid Product: the FDA-approved package insert, medication guide, and labeling, and a statement directing patients or caregivers to speak with a licensed Health Care Provider;

c. Provide information or support the provision of information as expressly required by law or any state or federal government agency with jurisdiction in the state where the information is provided. Teva may, in relation to its expressly required participation in the Transmucosal Immediate Release Fentanyl ("TIRF") Risk Evaluation and Mitigation Strategy ("REMS") Program, remain involved in the preparation of materials and training concerning the process for enrollment in the TIRF REMS Program;

d. Provide the following by mail, electronic mail, on or through Teva's corporate or product websites or through other electronic or digital methods: FDA-approved package insert, medication guide, approved labeling for Opioid Products or other prescribing information for Opioid Products that are published by a state or federal government agency with jurisdiction in the state where the information is provided;

e. Provide scientific and/or medical information in response to an unsolicited request by a Health Care Provider consistent with the standards set forth in the FDA's Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011), as updated or amended by the FDA, and Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* (Jan. 2009), as updated or amended by the FDA;

f. Provide a response to any unsolicited question or request from a patient or caregiver, directing the patient or caregiver to the FDA-approved labeling or to speak with a licensed Health Care Provider without describing the safety or effectiveness of Opioids or any Opioid Product or naming any specific provider or healthcare institution; or directing the patient or caregiver to speak with their insurance carrier regarding coverage of an Opioid Product;

g. Provide Health Care Economic Information, as defined at 21 U.S.C. § 352(a), to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis consistent with standards set forth in the FDA's Draft Questions and Answers Guidance for Industry and Review Staff, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities* (Jan. 2018), as updated or amended by the FDA;

h. Provide information relating solely to the pricing of any Opioid Product;

i. Provide information, through a product catalog or similar means, related to an Opioid or Opioid Product, including, without limitation, pricing information, weight, color, shape, packaging size, type, reference listed drug, National Drug Code ("NDC") label, and such other descriptive information (including information set forth in a standard Healthcare Distribution Alliance Form or technical data sheet and the FDA approval letter) sufficient to identify the products available, to place an order for a product, and to allow the product to be loaded into a customer's inventory and ordering system or Third Party pricing compendia;

j. Sponsor or provide financial support or In-Kind Support for an accredited or approved continuing medical education program required by either an FDA-approved REMS program or other federal or state law or regulation applicable in the state where the program is provided through an independent Third Party, which shall be responsible for the continuing medical education program's content without the participation of Teva;

k. Provide information in connection with patient support information on co-pay assistance and managing pain in End-of-Life Care and/or Cancer-Related Pain Care relating to the use of Opioids for managing such pain, as long as the information identifies Teva as the source of the information; and

l. Provide rebates, discounts, and other customary pricing adjustments to DEA-registered customers and contracting intermediaries, such as Buying Groups, Group Purchasing Organizations, and Pharmacy Benefit Managers, except as prohibited by Section II.G.

3. Teva shall not engage in the following specific Promotional activity relating to any products indicated for the treatment of Opioid-induced side effects (for the avoidance of doubt, "Opioid-induced side effects" does not include addiction to Opioids or Opioid Products):

a. Employing or contracting with sales representatives or other persons to Promote products indicated for the treatment of Opioid-induced side effects to Health Care Providers or patients;

b. Using speakers, key opinion leaders, thought leaders, lecturers, and/or speaking events to Promote products indicated for the treatment of Opioid-induced side effects;

c. Sponsoring, or otherwise providing financial support or In-Kind Support to medical education programs that Promote products indicated for the treatment of Opioid-induced side effects; or

d. Creating, sponsoring, or otherwise providing financial support or In-Kind Support for advertisements that Promote products indicated for the treatment of Opioid-induced side effects, including but not limited to internet advertisements or similar content, and providing hyperlinks or otherwise directing internet traffic to advertisements.

4. Notwithstanding subsection II.B.3 directly above, Teva may Promote products for the treatment of Opioid-induced side effects (i) so long as such Promotion does not associate the product with Opioids or Opioid Products, or (ii) where such Promotion concerns a product's indication to reverse overdoses and/or treat Opioid addiction. Nothing herein shall prevent Teva from linking to the FDA label associated with a product.

5. Treatment of Pain

a. Teva shall not, either through Teva or through Third Parties, engage in Promotion of the Treatment of Pain in a manner that encourages the utilization of Opioids or Opioid Products.

b. Teva shall not, either through Teva or through Third Parties, Promote the concept that pain is undertreated in a manner that encourages the utilization of Opioids or Opioid Products.

c. Teva shall not disseminate Unbranded Information, including Unbranded Information about a medical condition or disease state, that contains links to branded information about Opioid Products or otherwise Promotes Opioids or Opioid Products.

6. Notwithstanding subsection II.B.5 directly above, Teva may Promote or provide educational information about the Treatment of Pain with non-Opioid products or therapies, including Promoting or providing educational information about such non-Opioid products or therapies as alternatives to Opioid use, or as part of multimodal therapy which may include Opioid use, so long as such non-Opioid Promotional or educational information does not Promote Opioids or Opioid Products.

C. No Financial Reward or Discipline Based on Volume of Opioid Sales

1. Teva shall not provide financial incentives to its sales and marketing employees or discipline its sales and marketing employees based upon sales volume or sales quotas for Opioid Products. For the avoidance of doubt, this provision shall not prohibit financial incentives (*e.g.*, customary raises or bonuses) based on the performance of the overall company or business segment, as measured by EBITDA, revenue, cash flow, or other similar financial metrics.

2. Teva shall not offer or pay any remuneration (including any kickback, bribe, or rebate) directly or indirectly, to or from any person in return for the prescribing, sale, or use of an Opioid Product. For the avoidance of doubt, this provision shall not prohibit rebates or chargebacks to the extent permitted by other sections of this Consent Judgment.

3. Teva's compensation policies and procedures shall be designed to ensure compliance with this Consent Judgment and other legal requirements.

D. Ban on Funding/Grants to Third Parties

1. Teva shall not, directly or indirectly, provide financial support or In-Kind Support to any Third Party for Promotion of or education about Opioids, Opioid Products, or products indicated for the treatment of Opioid-induced side effects (subject to subsections II.B.2, 4 and 6). For the avoidance of doubt, this provision does not prohibit support expressly allowed by this Consent Judgment or required by a federal or state agency.

2. Teva shall not create, sponsor, provide financial support or In-Kind Support to, or otherwise operate or control any medical society or patient advocacy group that primarily engages in conduct that Promotes Opioids or Opioid Products.

3. Teva shall not provide links to any Third Party website or materials or otherwise distribute materials created by a Third Party for the purpose of Promoting Opioids, Opioid Products, or products indicated for the treatment of Opioid-induced side effects (subject to subsections II.B.2, 4 and 6).

4. Teva shall not use, assist, or employ any Third Party to engage in any activity that Teva itself would be prohibited from engaging in pursuant to this Consent Judgment.

5. Teva shall not enter into any contract or agreement with any person or entity or otherwise attempt to influence any person or entity in such a manner that has the purpose or reasonably foreseeable effect of limiting the dissemination of information regarding the risks and side effects of using Opioids.

6. Teva shall not compensate or provide In-Kind Support to Health Care Providers (other than Teva employees) or organizations to advocate for formulary access or treatment guideline changes for the purpose of increasing access to any Opioid Product through third-party payers, *i.e.*, any entity, other than an individual, that pays or reimburses for the dispensing of prescription medicines, including but not limited to managed care organizations and pharmacy benefit managers. Nothing in this provision, however, prohibits Teva from using independent contractors who operate under the direction of Teva to provide information to a payor, formulary committee, or other similar entity as permitted in subsection II.B.2 provided that any such persons are bound by the terms of this Consent Judgment. Nor does this provision prohibit the payment of customary rebates or other pricing concessions to third-party payers, including state Medicaid programs, as part of an overall pricing agreement.

7. No officer or executive management-level employee of Teva may concurrently serve as a director, board member, employee, agent, or officer of any entity other than Teva Pharmaceutical Industries Ltd. or a direct or indirect wholly-owned subsidiary thereof, that primarily engages in conduct that Promotes Opioids, Opioid Products, or products indicated for the treatment of Opioid-related side effects. For the avoidance of doubt, nothing in this provision shall preclude an officer or executive management-level employee of Teva from concurrently serving on the board of a hospital.

8. Teva shall play no role in appointing persons to the board, or hiring persons to the staff, of any entity that primarily engages in conduct that Promotes Opioids, Opioid Products, or products indicated for the treatment of Opioid-induced side effects. For the avoidance of doubt, nothing in this paragraph shall prohibit Teva from fully and accurately responding to unsolicited

requests or inquiries about a person's fitness to serve as an employee or board member at any such entity.

9. For the avoidance of doubt:

a. Nothing in this Section II.D shall be construed or used to prohibit Teva from providing financial or In-Kind Support to:

(i) medical societies and patient advocate groups, who are principally involved in issues relating to (I) the treatment of OUD; (II) the prevention, education and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (III) rescue medications for opioid overdose; or

(ii) universities, medical institutions, or hospitals, for the purpose of addressing, or providing education on, issues relating to (I) the treatment of OUD; (II) the prevention, education and treatment of opioid abuse, addiction, or overdose, including medication-assisted treatment for opioid addiction; and/or (III) rescue medications for opioid overdose;

(iii) the American Medical Association (AMA), the American Cancer Society (ACS) or any other medical society solely dedicated to cancer treatment; or

(iv) trade associations including, without limitation, PhRMA (Pharmaceutical Research and Manufacturers of America), HDA (Healthcare Distribution Alliance), AAM (Association for Accessible Medications), PCMA (Pharmaceutical Care Management Association), and NACDS (National Association of Chain Drug Stores), or successor organizations to any of the foregoing.

b. The prohibitions in this Section II.D shall not apply to engagement with Third Parties based on activities related to (i) medications with an FDA-approved label that lists only the treatment of opioid abuse, addiction, dependence and/or overdose as their "indications and usage," to the extent they are sold to addiction treatment facilities; (ii) raw materials, APIs and/or immediate precursors used in the manufacture or study of Opioids or Opioid Products, but only when such materials, APIs and/or immediate precursors are sold or marketed exclusively to DEA registrants or sold outside the United

States or its territories; or (iii) education warning about drug abuse or promoting prevention or treatment of drug misuse.

c. Teva will be in compliance with subsections II.D.2 and II.D.3 with respect to support of an individual Third Party to the extent that the State of Rhode Island determines that such support does not increase the risk of the inappropriate use of Opioids and that Teva has not acted for the purpose of increasing the use of Opioids.

E. Lobbying Restrictions

1. Teva shall not Lobby for the enactment of any federal, state, or local legislative or regulatory provision that:

a. encourages or requires Health Care Providers to prescribe Opioids or sanctions Health Care Providers for failing to prescribe Opioids or failing to treat pain with Opioids; or

b. pertains to the classification of any Opioid or Opioid Product as a scheduled drug under the Controlled Substances Act.

2. Teva shall not Lobby against the enactment of any federal, state or local legislative or regulatory provision that supports:

a. The use of non-pharmacologic therapy and/or non-Opioid pharmacologic therapy to treat chronic pain over or instead of Opioid use, including but not limited to third party payment or reimbursement for such therapies;

b. The use and/or prescription of immediate release Opioids instead of extended release Opioids when Opioid use is initiated, including but not limited to third party reimbursement or payment for such prescriptions;

c. The prescribing of the lowest effective dose of an Opioid, including but not limited to third party reimbursement or payment for such prescription;

d. The limitation of initial prescriptions of Opioids to treat acute pain;

e. The prescribing and other means of distribution of naloxone to minimize the risk of overdose, including but not limited to third party reimbursement or payment for naloxone;

f. The use of urine testing before starting Opioid use and annual urine testing when Opioids are prescribed, including but not limited to third party reimbursement or payment for such testing;

g. Evidence-based treatment (such as using medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for OUD, including but not limited to third party reimbursement or payment for such treatment; or

h. The implementation or use of Opioid drug disposal systems.

3. Teva shall not Lobby against the enactment of any federal, state or local legislative or regulatory provision expanding the operation or use of prescription drug monitoring programs ("PDMPs"), including but not limited to provisions requiring Health Care Providers to review PDMPs when Opioid use is initiated and with every prescription thereafter.

4. Notwithstanding the foregoing restrictions in subsections II.E.1-3, the following conduct is not restricted:

a. Lobbying against the enactment of any provision of any state, federal, municipal, or county taxes, fees, assessments, or other payments;

b. Challenging the enforcement of, or suing for declaratory or injunctive relief with respect to legislation, rules or regulations referred to in subsection II.E.1;

c. Communications made by Teva in response to a statute, rule, regulation, or order requiring such communication;

d. Communications by a Teva representative appearing before a federal or state legislative or administrative body, committee, or subcommittee as a result of a mandatory order or subpoena commanding that person to testify;

e. Responding, in a manner consistent with this Consent Judgment, to an unsolicited request for the input on the passage of legislation or the promulgation of any rule or regulation when such request is submitted in writing specifically to Teva from a government entity directly involved in the passage of that legislation or promulgation of that rule or regulation;

f. Lobbying for or against provisions of legislation or regulation that address other subjects in addition to those identified in subsections

II.E.1-3, so long as Teva does not support specific portions of such legislation or regulation covered by subsection II.E.1 or oppose specific portions of such legislation or regulation covered by subsections II.E.2-3;

g. Communicating with a federal or state agency in response to a Federal Register or similar notice or an unsolicited federal or state legislative committee request for public comment on proposed legislation;

h. Responding to requests from the DEA, the FDA, or any other federal or state agency, and/or participating in FDA or other agency panels at the request of the agency; and

i. Participating in meetings and other proceedings before the FDA, FDA advisory committee or other FDA committee in connection with the approval, modification of approval, or oversight of Teva's own products.

5. Teva shall provide notice of the prohibitions in Section II.E to all employees engaged in Lobbying; incorporate the prohibitions in Section II.E into trainings provided to Teva employees engaged in Lobbying; and certify that it has provided such notice and trainings to Teva employees engaged in Lobbying.

F. Monitoring and Reporting of Off-Label Use

1. Teva shall monitor for off-label prescribing of its brand Opioid Products in the United States as provided for in the TIRF REMS Program..

2. Upon request of one of the following, Teva shall provide the requestor with the data and analysis described in Subsection II.F.1, to be used for law enforcement, counter-detailing, academic or medical research, or public health and other non-commercial purposes: Rhode Island Attorney General or other law enforcement agency, Rhode Island medical board, Rhode Island board of pharmacy, Qualified Researchers, medical and pharmacy directors of health systems or clinics, medical associations, and other public health officials, including but not limited to city health authorities, county medical directors, and Rhode Island public health authorities.

3. Teva shall provide the data and analysis described in Subsection VI.E.1 in chart format, including breakdown of prescriptions by year, diagnosis, and county.

G. Ban on High Dose Opioids.

1. After any related commercial commitments existing on the Effective Date have expired, Teva shall not manufacture, promote, or distribute any oxycodone pill that exceeds 40 milligrams.

H. Ban on Prescription Savings Programs

1. Teva shall not directly or indirectly offer any discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product. This does not preclude Teva from offering discounts or rebates to commercial partners on entire portfolios of products, including providing discounts, coupons, rebates, or other methods for use by retail chain pharmacies, such as CVS, Walgreens, Rite Aid and the like.

2. Teva shall not directly or indirectly provide financial support to any Third Party for discounts, coupons, rebates, or other methods which have the effect of reducing or eliminating a patient's co-payments or the cost of prescriptions (*e.g.*, free trial prescriptions) for any Opioid Product.

I. Monitoring and Reporting of Direct and Downstream Customers.

1. Teva shall operate an effective monitoring and reporting system in compliance with federal law, that shall include processes and procedures that:

   a. Utilize all reasonably available transaction information to identify a Suspicious Order of an Opioid Product by a direct customer;

   b. Utilize all reasonably available Downstream Customer Data to identify whether a downstream customer poses a material risk of diversion of an Opioid Product;

   c. Utilize all information Teva receives that bears upon a direct customer's or a downstream customer's diversion activity or potential for diversion activity, including reports by Teva's employees, customers, Health Care Providers, law enforcement, state, tribal, or federal agencies, or the media; and

   d. Upon request (unless otherwise required by law), report to the Rhode Island Attorney General or State controlled substances regulatory agency any direct customer or downstream customer in Rhode Island identified as part of the monitoring required by (a)-(c), above, and any customer relationship in such State terminated by

Teva relating to diversion or potential for diversion. These reports shall include the following information, to the extent known to Teva:

(i) The identity of the downstream registrant and the direct customer(s) identified by Teva engaged in the controlled substance transaction(s), to include each registrant's name, address, business type, and DEA registration number;

(ii) The dates of reported distribution of controlled substances by direct customers to the downstream registrant during the relevant time period;

(iii) The drug name, drug family or NDC and dosage amounts reportedly distributed;

(iv) The transaction or order number of the reported distribution; and

(v) A brief narrative providing a description of the circumstances leading to Teva's conclusion that there is a risk of diversion.

2. Teva shall not provide to any direct customer an Opioid Product to fill an order identified as a Suspicious Order unless Teva investigates and finds that the order is not suspicious.

3. Upon request, Teva shall provide cooperation and assistance to any federal, state or local law enforcement investigations of potential diversion or suspicious circumstances involving Opioid Products, including criminal law enforcement agencies, drug control agencies, professional licensing boards, and Attorney General's offices.

4. Teva agrees that it will refrain from providing an Opioid Product directly to a retail pharmacy or Health Care Provider.

J. Miscellaneous Terms

1. To the extent that any provision in this Consent Judgment conflicts with federal or relevant state law or regulation, the requirements of the law or regulation will prevail. To the extent that any provision in this Consent Judgment is in conflict with federal or relevant state law or regulation such that Teva cannot comply with both the law or regulation and the provision of this Consent Judgment, Teva may comply with such law or regulation.

2. Teva will enter into this Consent Judgment solely for the purpose of settlement, and nothing contained therein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Teva expressly denies. No part of this Consent Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Teva. This Consent Judgment is not intended for use by any Third Party for any purpose, including submission to any court for any purpose.

3. For the avoidance of doubt, this Consent Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Teva in any action, and nothing in this Consent Judgment shall be construed or used to prohibit Teva in any way whatsoever from taking legal or factual positions with regard to any Opioid Product(s) in litigation or other legal or administrative proceedings.

4. Nothing in this Consent Judgment shall be construed to limit or impair Teva's ability (a) to communicate its positions and respond to media inquiries concerning litigation, investigations, reports, or other documents or proceedings relating to Teva or its Opioid Products, or (b) to maintain a website explaining its litigation positions and responding to allegations concerning its Opioid Products.

5. Nothing in this Consent Judgment shall prohibit Teva from divesting any Opioid or Opioid Product, in each case, including providing technical development services, transferring know-how and patents, and/or providing such other support services in connection therewith.

6. This Consent Judgment applies to the manufacture, sales, Promotion, marketing and distribution by Teva within the United States and its territories or involving Health Care Providers.

7. Upon the request of the Attorney General of the State of Rhode Island, Teva shall provide the Attorney General of the State of Rhode Island with copies of the following, within 30 days of the request:

   a. Any litigation or civil or criminal law enforcement subpoenas or Civil Investigative Demands relating to Teva's Opioid Product(s); and

   b. Warning or untitled letters issued by the FDA regarding Teva's Opioid Product(s) and all correspondence between Teva and the FDA related to such letters.

8. The parties by stipulation may agree to a modification of this Consent Judgment; provided that the parties may jointly agree to a modification only by a written instrument signed by or on behalf of both Teva and the Attorney General of the State of Rhode Island.

9. If, after the Effective Date, Teva, or its distributor subsidiary Anda, Inc. enters into any collective resolution of substantially all opioid claims brought by states, counties, and municipalities (a "Global Resolution") that contains injunctive relief terms that are more favorable than the terms of this Consent Judgment, then this Consent Judgment will be revised to contain such more favorable injunctive relief terms. Teva and/or Anda shall provide the State a copy of any Other State Settlement within thirty (30) days of its effective date.

K. Compliance with State Laws and Regulations Relating to the Sale, Promotion, and Distribution of Any Opioid Product

1. Subject to subsection II.G.1 above, Teva shall continue to comply with all applicable state laws and regulations that relate to the sale, Promotion, distribution, and disposal of Opioids or Opioid Products, including but not limited to:

a. Rhode Island Controlled Substances Act, including all guidance issued by the applicable state regulator(s);

b. Rhode Island Consumer Protection Laws; and

c. Rhode Island laws and regulations related to opioid prescribing, distribution, and disposal.

## III. Clinical Data Transparency

A. Data to Be Shared

1. Teva shall continue to share truthful and balanced summaries of the results of all Teva-Sponsored Studies through its publicly available website (*see* https://www.tevapharm.com/teva-clinical-trials):

a. "Teva-Sponsored Studies" means pre-marketing clinical research and post-marketing clinical research that Teva "takes responsibility for and initiates" as "sponsor," as "sponsor" is defined in 21 C.F.R. § 312.3(b), and that involves an intervention with human subjects with an Opioid Product.

b. The summaries may include redactions to protect personal identifying information, trade secret and confidential commercial information, and information that may provide a road map for defeating a product's abuse-deterrent properties.

2. With respect to any Teva-Sponsored Studies relating to any new Teva Opioid Product or new indication for an existing Teva Opioid Product, Teva shall, within 6 months after regulatory approval or 18 months after study completion, whichever occurs later, make the following clinical data that is reasonably accessible and in its possession, custody, and control available through a third-party data archive that makes clinical data available to Qualified Researchers with a bona fide scientific research proposal:

   a. Fully analyzable data set(s) (including individual de-identified participant-level data);

   b. The clinical study report(s) redacted for commercial or personal identifying information;

   c. The full protocol(s) (including the initial version, final version, and all amendments); and

   d. Full statistical analysis plan(s) (including all amendments and documentation for additional work processes).

   e. Data related to Investigator Sponsored Studies are not subject to the requirements in Section III.

B. Third-Party Data Archive

1. The third-party data archive referenced above shall have a panel of reviewers with independent review authority to determine whether the researchers are qualified, whether a research application seeks data for bona fide scientific research, and whether a research proposal is complete.

2. The panel may exclude research proposals with a commercial interest.

3. Teva shall not interfere with decisions made by the staff or reviewers associated with the third-party data archive.

4. Any data sharing agreement with a Qualified Researcher who receives shared data via the third-party data archive shall contain contact information for Teva's pharmacovigilance staff. Every agreement shall require the lead Qualified Researcher to inform Teva's pharmacovigilance staff within 24 hours of any determination that research findings could bear on the risk-

benefit assessment regarding the product. The lead Qualified Researcher may also share findings bearing on the risk-benefit assessment regarding the product with regulatory authorities. Teva's pharmacovigilance staff shall take all necessary and appropriate steps upon receipt of such safety information, including but not limited to notifying the appropriate regulatory authorities or the public.

5. Teva shall bear all costs for making data and/or information available to the third-party data archive.

## IV. Compliance

A. Compliance Duration

1. Sections II and III of this Exhibit shall be effective for 13 years from the Effective Date.

2. Nothing in this Consent Judgment shall relieve Teva of its independent obligation to fully comply with the laws of the State of Rhode Island after expiration of the 13-year period specified in this subsection.

B. Compliance Deadlines

1. Teva must be in full compliance with the provisions included in this Consent Judgment by the Effective Date. Nothing herein shall be construed as permitting Teva to avoid existing legal obligations.

## V. Enforcement

A. If the State believes that Teva is not in compliance with any term of this Final Consent Order, then the State shall:

1. Provide written notice specifying the reason(s) why the State believes Teva is not in compliance with this Final Consent Order; and

2. Allow Teva at least thirty (30) days to attempt to cure such alleged non-compliance (the "Cure Period").

B. The State may not commence a proceeding to enforce compliance with this Final Consent Order before the expiration of the Cure Period, provided that the State may take any action if the State believes that, because of the specific practice, a threat to health or safety of the public requires immediate action.

C. Teva agrees to venue for any proceedings related to this paragraph in the Court in which the State of Rhode Island files this Consent Judgment.

# Exhibit H

# Consent Judgment and Stipulation of Dismissal with Prejudice

**Consent Judgment and Stipulation of Dismissal with Prejudice**

| | |
|---|---|
| STATE OF RHODE ISLAND<br>PROVIDENCE, SC | SUPERIOR COURT |
| STATE OF RHODE ISLAND, by and through, PETER F. NERONHA, ATTORNEY GENERAL, *Plaintiff*,<br>v.<br>PURDUE PHARMA L.P. *et al.*, *Defendants*; | C.A. NO.: PC2018-4555 |

**RECITATIONS OF THE PARTIES:**

1. The State of Rhode Island ("*Plaintiff*") brought the above-captioned action (the "*Action*") against Defendants, Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) (collectively, "*Settling Teva Defendants*"), alleging claims sounding in negligence, public nuisance, fraud, negligent misrepresentation and unjust enrichment, as set forth in the Third Amended Complaint, a copy of which is attached hereto as Exhibit A, filed on March 21, 2022. Settling Teva Defendants deny these allegations and deny all liability to Plaintiff.

2. The Plaintiff and Settling Teva Defendants (collectively, the "*Parties*" and each a "Party") entered into a consensual resolution of the Action as between them pursuant to a settlement agreement entitled Teva Rhode Island Statewide Opioid Settlement Agreement, executed as of March 21, 2022 (the "*Teva Rhode Island Agreement*"), a copy of which is attached hereto as Exhibit B. Each Party warrants and represents that it engaged in arm's-length negotiations between themselves in good faith. In executing the Teva Rhode Island Settlement Agreement, the Parties intend to effect a good-faith settlement.

3. The Teva Rhode Island Agreement becomes effective by its terms upon the entry of this Final Consent Judgment (the "*Judgment*" or "*Order*") by the Court without

adjudication of any issue of fact or law arising from the Third Amended Complaint, and without finding or admission of wrongdoing or liability of any kind.

4. Pursuant to the Teva Rhode Island Agreement, the Rhode Island Monetary Relief Payment shall be $21,000,000.00, according to the schedule and terms set forth Section III.B.1 of the Teva Rhode Island Agreement.

5. Pursuant to the Teva Rhode Island Agreement, Teva shall provide Settlement Product to the State of Rhode Island free of charge for a period of ten (10) years, in the quantities and according to the schedule set forth in Section III.D of the Teva Rhode Island Agreement.

6. Pursuant the Teva Rhode Island Agreement, Teva shall provide Injunctive Relief to the State as set forth in Section IV.A of the Teva Rhode Island Agreement.

7. As set forth in Section X.D of the Teva Rhode Island Agreement, if, after execution of the Teva Rhode Island Agreement, there is a collective resolution of substantially all Claims against Teva via a global settlement under which the State of Rhode Island would have received more favorable terms as those terms are described in Section X.D of the Teva Rhode Island Agreement, Teva shall provide the State of Rhode Island with (1) the greater monetary amount, (2) the more favorable payment terms as set forth in Section X.D of the Teva Rhode Island Agreement, and (3) the greater product amount as valued by the terms of the Teva Rhode Island Agreement.

8. Pursuant to the Teva Rhode Island Agreement, the Teva Attorney Fee payment shall be $5,460,349.00, subject to approval of the Honorable Judge Richard Licht or his successor or such other judge as may be assigned to the underlying matter in the Providence County Superior Court.

9. Pursuant to the Teva Rhode Island Agreement, the Teva Attorney Expense payment shall be up to a cap of $3,000,000.00.

10. The Parties consent to this Court retaining continuing jurisdiction for the limited purpose of enforcing the Teva Rhode Island Agreement and this Consent Judgment.

NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

1. The Parties to this agreement are the State of Rhode Island, acting through its Attorney General and Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida).

2. This Court has jurisdiction over the subject matter of this lawsuit and over all the Parties.

3. Entry of this Order is in the public interest and reflects a negotiated settlement among the Parties, the terms of which shall be governed by the laws of the State of Rhode Island.

4. The Court finds that the Teva Rhode Island Agreement was entered into in good faith.

5. Settling Teva Defendants are willing to enter into this Order regarding the Covered Conduct defined in the Teva Rhode Island Agreement to resolve the Attorney General's claims under Rhode Island statutory and common law as to the matters addressed in this Order and thereby avoid significant expense, inconvenience, and uncertainty.

6. Settling Teva Defendants are entering into this Order solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Settling Teva Defendants expressly deny.

7. Settling Teva Defendants do not admit any violation of common or statutory law, and do not admit any wrongdoing that was or could have been alleged by the Attorney General before the date of the Order under those laws.

8. It is the intent of the Parties that this Order not be admissible in other cases against Settling Teva Defendants or binding on Settling Teva Defendants in any respect other than in connection with the enforcement of this Order or the Teva Rhode Island Agreement.

9. This Order is made without adjudication of any issue of fact or law arising from the Third Amended Complaint or finding of liability of any kind. No part of this Order, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Settling Teva Defendants.

10. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose, except as provided in Section IX.A of the Teva Rhode Island Agreement. No part of this Order or of the Teva Rhode Island Agreement shall create a private cause of action or confer any right to any third party for violation of any federal or state statute.

11. This Order shall not be construed or used as a waiver or limitation of any defense otherwise available to Settling Teva Defendants in any other action, or of Settling Teva Defendants' right to defend from, or make any arguments in, any private individual action, class claims or suits, or any other governmental or regulatory action relating to the subject matter or terms of this Order.

12. By this Judgment, the Teva Rhode Island Agreement is hereby approved by the Court.

13. The Rhode Island Monetary Relief shall be used solely for Opioid Abatement and Remediation by the State and the Participating Subdivisions, as those terms are

defined in, and in accordance with, the provisions of Section III.C of the Teva Rhode Island Agreement.

14. Teva shall pay the Rhode Island Monetary Relief to the State of Rhode Island and to the Participating Subdivisions pursuant to the schedule set forth in Section III.B of the Teva Rhode Island Agreement. The first payment shall be made within thirty (30) calendar days of the entry of this Order and the second and subsequent payments (Payments 2-13) shall be made annually on or before January 1, 2023 to January 1, 2034. All payments shall be paid into the Rhode Island Qualified Settlement Fund ("the Fund").

15. The Fund shall be structured and operated in a manner so that it qualifies as a "Qualified Settlement Fund" within the meaning of section 468B of the Internal Revenue Code of 1986, as amended, as described in Treasury Regulations Section 1.468B-1 et seq., and shall remain subject to the continuing jurisdiction of this Court.

16. For the first payment, the Court appoints Joseph F. Rice of Motley Rice, LLC to serve as Trustee and Administrator of the Rhode Island Qualified Settlement Fund ("Fund Administrator") for purposes of Treasury Regulations Section l.468B-2(k)(3). The Fund shall be held at the following financial institution, as hereby approved by the Court: Wells Fargo Bank, N.A., Account Number 2411745058, Federal Tax Identification Number 87-4156403. For each subsequent payment, Rhode Island shall designate the Qualified Settlement Fund and Qualified Settlement Fund Administrator and provide Teva with the account information for purposes of making the required payments under the Rhode Island Teva Agreement and this Order.

17. The Fund Administrator shall be responsible for making any necessary tax filings and payments of taxes, estimated taxes, and associated interest and penalties, if any, by the Fund. The Fund Administrator shall be responsible for responding to any questions from, or audits regarding such taxes by, the Internal Revenue Service or any state or local tax authority, as well as questions from the Department of Labor. The Fund Administrator shall also be responsible for complying with all tax information reporting and withholding requirements with respect to payments made by the Fund, as well as paying any associated interest and penalties. All such tax, interest, and penalty payments and all expenses and costs incurred in connection with taxation of the Fund (including, without limitation, expenses of tax attorneys and accountants) shall be paid from the Fund and shall be considered administrative costs of the settlement. No bond shall be required.

18. The Court shall retain jurisdiction and may hold any further proceedings and enter any separate orders, necessary to effectuate the provisions of the Teva Rhode Island Agreement and resolve any disputes thereunder. The State and its counsel shall file their Motion for Approval of Costs and Fees within thirty days of entry of this Consent Judgment and the Court will determine further process.

19. The entry of this Consent Judgment constitutes a full and final dismissal with prejudice of the Action as between the State and Settling Teva Defendants. This Court shall retain jurisdiction over the Parties for the limited purpose of enforcing the Teva Rhode Island Agreement and this Order.

**So ORDERED this _____ day of March, 2022.**

Enter: By Order:

_____ _____

Richard A. Licht, Associate Justice Clerk

**APPROVED, AGREED TO AND PRESENTED BY:**

**For the State of Rhode Island**
Peter F. Neronha, Attorney General
By his attorney,

*Counsel for the State of RI*

PETER F. NERONHA
ATTORNEY GENERAL

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**For Teva Pharmaceuticals USA, Inc., Cephalon, Inc., and the Actavis Generic Entities:**

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|---|---|
| STATE OF RHODE ISLAND<br>PROVIDENCE, SC | SUPERIOR COURT |
| STATE OF RHODE ISLAND, by and through, PETER F. NERONHA, ATTORNEY GENERAL,<br>*Plaintiff*,<br>v.<br><br>PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; RHODES PHARMACEUTICALS L.P.; RHODES TECHNOLOGIES; RHODES TECHNOLOGIES INC.; RICHARD S. SACKLER; INSYS THERAPEUTICS, INC.; JOHN N. KAPOOR; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; WATSON LABORATORIES, INC.; WARNER CHILCOTT COMPANY, LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC; ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC; ACTAVIS KADIAN LLC; ACTAVIS LABORATORIES UT, INC., F/K/A WATSON LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC., F/K/A WATSON LABORATORIES, INC.-FLORIDA; ALLERGAN PLC F/K/A ACTAVIS PLC F/K/A ALLERGAN, INC.; ALLERGAN FINANCE, LLC F/K/A ACTAVIS INC. F/K/A WATSON PHARMACEUTICALS, INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; MALLINCKRODT PLC; MALLINCKRODT, LLC; SPECGX, LLC; CARDINAL HEALTH, INC.; MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY; and AMERISOURCEBERGEN DRUG CORPORATION,<br>*Defendants*; | C.A. NO.: PC2018-4555 |

**THIRD AMENDED COMPLAINT**

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## I. PRELIMINARY STATEMENT

1. The State of Rhode Island, by an through its Attorney General, Peter F. Neronha, ("Rhode Island" or "State"), brings this action pursuant to his statutory and common law authority to redress Purdue Pharma, L.P.'s, Purdue Pharma Inc.'s, the Purdue Frederick Company's (together, "Purdue"); Rhodes Pharmaceuticals, L.P.'s, Rhodes Technologies, Rhodes Technologies Inc.'s ("together, "Rhodes"); Richard S. Sackler ("Sackler," and with Purdue and Rhodes, the "Purdue Defendants');  Insys Therapeutics, Inc.; John N. Kapoor ("Kapoor," and with Insys Therapeutics, Inc., "Insys"); Teva Pharmaceuticals USA, Inc., Cephalon, Inc., Watson Laboratories, Inc., Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida);[1] and Allergan plc f/k/a Actavis plc f/k/a Allergan Inc., Allergan Finance, LLC f/k/a Actavis Inc. f/k/a Watson Pharmaceuticals, Inc., Allergan Sales, LLC, and Allergan USA, Inc. ("Allergan")  Mallinckrodt plc; Mallinckrodt, LLC, SpecGX, LLC (together, "Mallinckrodt," and with the Purdue Defendants, Insys, Allergan and Teva , the "Marketing Defendants'"); McKesson Corporation d/b/a McKesson Drug Company ("McKesson") Cardinal Health, Inc.'s ("Cardinal"), and AmerisourceBergen Drug Corporation ("AmerisourceBergen," and with McKesson and Cardinal, the "Distributor Defendants") campaign to unlawfully promote and

[1] Watson Laboratories, Inc.; Warner Chilcott Company LLC, Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City), Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) are together the "Former Actavis Entities."  The Former Actavis Entities, with Cephalon, Inc., and Teva Pharmaceuticals USA, Inc. are "Teva")

distribute opioids in Rhode Island.

2. Prescription opioids are narcotics. They are derived from and possess properties like opium and heroin, they are regulated as controlled substances, and they cause addiction. While opioids can work to dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience often prolonged withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

3. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[2] This country's history of opioid use and addiction had counseled against widespread use of these drugs. Rampant prescription of "patent medicines" containing opium, morphine, and later heroin, led to widespread addiction following the Civil War and the turn of the last century, where addiction rates as high as 1 in 200 Americans eventually led to the adoption of the 1914 Harrison Narcotics Tax Act, which imposed quotas on the importation of opium derivatives.[3] More recently, heroin and prescription drug outbreaks followed the Vietnam War. Both illegal

[2] In this Third Amended Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

[3] Erick Trickey, "Inside the Story of America's 19th Century Opiate Addiction," *Smithsonian.com*, January 4, 2018, https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/

heroin and abuse of then-popular prescription opioids like Numorphan[4] and Percodan[5] thrived in the 1970s. Given this experience with opioids' addictive properties, the market for prescription opioids was sharply restricted as a matter of doctors' practice and public health and safety.

4. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids more liberally. This required persuading prescribers and patients that opioids were appropriate for prolonged use for more widespread, less severe pain conditions, like back pain, migraines, and arthritis. Purdue helped cultivate a narrative that pain was undertreated and pain treatment should be a higher priority for health care providers. This paved the way for increased prescribing of opioids for chronic pain. As part of this strategy, Purdue misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

5. The Purdue Defendants aggressively marketed their opioids to physicians in Rhode Island and nationwide, knowing that its in-person marketing, or "detailing" to doctors was effective. Numerous studies indicate that this marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

6. Between the 1990s and 2011, prescriptions of oxycodone, an active ingredient in opioid drugs manufactured by the Purdue Defendants more than doubled in the United States, much of which was sold in generic forms by Defendants Rhodes, Allergan Teva, and Mallinckrodt. During the same time period, opioid prescriptions increased some 31% from

[4] Jon Fauber and Kristina Fiore, "Abandoned Painkiller Makes A Comeback, *Medpage Today*, May 10, 2015

[5] "Unwitting Addicts Discover That The Painkiller Percodan Bring An Agony of Its Own," *People*, November 19, 1979, *available at*: http://people.com/archive/unwitting-addicts-discover-that-the-painkiller-percodan-brings-an-agony-of-its-own-vol-12-no-21/

approximately 1.6 million to approximately 2.2 million. According to a U.S. Department of Health and Human Services Fact Sheet, "[i]n 2014, more than 240 million prescriptions were written for prescription opioids, which is more than enough to give every American adult their own bottle of pills."

7. The Purdue Defendants' deceptive marketing efforts continued over the next several years, eventually coming under investigation by a number of state and federal entities. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing OxyContin, and had to reimburse Rhode Island for $1.2 million in costs incurred by the Medicaid Assistance Program from 1995 to 2005. As laid out in its plea agreement, Purdue systematically misrepresented the risk of addiction, including promising that opioid addiction occurred in less than 1% of patients, and that opioids were not addictive when legitimately prescribed. This was how Purdue explained away what doctors had previously believed about opioids: it was not that opioids were not addictive, but rather opioids would not addict patients under a doctor's care.

8. Rather than reforming its opioid marketing to comply with the law after its 2007 plea and settlements, The Purdue Defendants continued to mislead and obfuscate. They spent hundreds of millions of dollars nationally on promotional activities and materials that continued to falsely deny or trivialize the risk of addiction and overstate the benefits of opioids. The Purdue Defendants continued to deceptively market opioids to prescribers through advertising, websites, and in-person sales calls. The Purdue Defendants also relied upon continuing medical education ("CME") seminars, non-credit education programs, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that were flawed and misleading, but seemed independent and therefore credible.

9. Through these efforts, the Purdue Defendants, and later, Teva and Mallinckrodt, were able to persuade prescribers that, even though opioids were addictive, that risk could be allayed by doctors carefully supervising their use by appropriate patients. Part of the Manufacturing Defendants' message was that doctors should treat the right patients: legitimate patients who took the drugs as directed (orally) to treat their pain, rather than abusers seeking to snort or inject the drugs for recreation. By defining the class of individuals who should not receive opioids as only these abusers, the Manufacturing Defendants gave prescribers a false sense of security that they could safely prescribe opioids to patients they trusted without fear that these patients would become addicted.

10. When faced with a rising tide of opioid addiction, overdose, and death – precisely the risks that they denied in their marketing – the Purdue Defendants falsely promoted its abuse-deterrent opioids as preventing abuse and diversion and "safe." They knew, and evidence showed, that the "abuse-deterrent" features of their opioids could be easily defeated, did not affect oral use, which is the most common means of abuse, and increased harmful outcomes, like injection or conversion to heroin. Purdue's marketing was intended to, and did, reassure prescribers who became concerned about addiction that they not only could continue to prescribe opioids, but also in fact needed to switch to their brands of opioids, thus preserving and expanding its market.

11. In the same vein, the Purdue Defendants also misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing. Upon information and belief, based on the reporting of an industry-wide practice, Purdue paid reimbursements known as "chargebacks" to wholesale distributors, and thereby obtained information about where their drugs were going as they progressed from wholesalers to retailers

and down the supply chain. The Manufacturing Defendants also had access to detailed prescribing data, which they monitored regularly to target and monitor their marketing efforts. Purdue failed to report suspicious orders or retailers from 2014 to the present, and upon information and belief, even earlier, that information obtained from the chargeback and prescribing data, as well as their own observations, would have revealed.

12. The Purdue Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Deceptive marketing caused prescribing not only of their opioids, but also of opioids as a class, to skyrocket. In 2015, Purdue reaped an estimated $2.4 billion in revenue, virtually all of it from opioids. Since its launch in 1996, OxyContin alone has generated $35 billion in sales.

13. Opioids are now among the most prescribed classes of drugs. In 2015 on an average day, more than 620,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales was for chronic opioid therapy, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

14. Prescriptions within Rhode Island exceeded the national average from 2006 through 2012, reaching a high in 2012 of 83.2 opioid prescriptions per 100 people.[6] Over this time period, Rhode Island's Medicaid program (the Medical Assistance Program) incurred over $6 million to pay for prescriptions of Purdue branded opioids, additional funds for Purdue's generic opioids. From July 2013 to February 2018, as well, the Medical Assistance Program paid over $350,000 for Rhodes Pharmaceuticals opioids, and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain. From May 23, 2014

[6] https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

through March 4, 2016, the State's Medical Assistance Program spent over $175,000 to pay for prescriptions of Insys opioids, as well. The Medical Assistance Program also paid $443,348 for Mallinckrodt branded and generic opioids from July 2013 to February 2018. The Medical Assistance Program also spent over $15 million over the last four years for medication assisted treatment—a number that will continue to grow.

15. Once a mass market for prescription opioids had been created, Distributor Defendants flooded it. Distributor Defendants are responsible for delivering opioids marketed and made by the opioid makers to pharmacies throughout the country. Distributor Defendants have a duty under state law to report and to not ship suspicious orders of controlled substances including orders of opioids that exceed reasonable volume or frequency, into Rhode Island. Yet, Distributor Defendants have supplied opioids in quantities that they knew or should have known exceed any legitimate market for opioids—even the wider market for chronic pain—and ignored red flags of suspicious orders of these drugs in Rhode Island. Upon information and belief, they routinely failed to do so, deepening the crisis of opioid abuse, addiction and death in the state.

16. Indeed, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. The Centers for Disease Control and Prevention ("CDC") concluded in 2016 that "for the vast majority of [chronic pain] patients, the known, serious, and too-often-fatal risks [of opioids] far outweigh the unproven and transient benefits."[7] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[8]

[7] Thomas R. Frieden et al., *Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline*, 374 New Eng. J. Med. 1501-1504 (2016).
[8] *Id.*

17. As a direct result of Defendants' conduct, the nation is now swept up in what the CDC called a "public health epidemic" and what the U.S. President deemed a "public health emergency."[9] The increased volume of opioid prescribing and distribution correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

18. Every day, 115 people die across the country from an opioid-related overdose and over 1,000 patients are given emergency treatment for misusing them. Many others are swept into a cycle of addiction and abuse with which they will struggle their entire lives. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 194,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

19. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk[] of … addiction"—"even at recommended doses"—of all opioids."[10] That same month, after a "systematic review of the best available evidence" by a panel excluding

[9] The New York Times, Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds, October 26, 2017, available at https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

[10] FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sep. 10, 2013); see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

experts with conflicts of interest, the CDC published the CDC Guideline For Prescribing Opioids For Chronic Pain (the "CDC Guideline"). The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[11] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[12] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.[13]

20. The CDC also noted that patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are approximately nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

21. Because Manufacturing Defendants convinced prescribers to disregard these known risks, in Rhode Island, the age-adjusted overdose rate in 2015 of 28.2 per 100,000 people ranks fifth in the nation. From 2014-2015, Rhode Island experienced a 24% one-year change in overdose deaths, the third highest change in America. The rate of deaths from *synthetic* opioids like fentanyl ranked third in the nation in 2015. From 2011 to 2016, as well, Rhode Island saw a

[11] CDC Guideline at 2.
[12] *Id.* at 21.
[13] Bradley C. Martin *et al.*, Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study, 26 J. Gen. Internal. Med. 1450 (2011).

303% increase in overdose fatalities.[14]

22. While opioids have been diverted through illicit prescribing and sales, it is the regular, legitimate prescribing of opioids that created and fueled this crisis. A study of 254 accidental opioid overdose deaths in Utah found that 92% had been receiving prescriptions from health care providers for chronic pain. Indeed, the majority of patients seeking treatment for opioid and heroin addiction nationally, and upon information and belief in Rhode Island, started with an opioid prescription for pain.[15] This market required both Purdue's efforts to position opioids as the "gold standard" of pain treatment, and Distributor Defendants' efforts to ensure pharmacies were able to dispense the heightened demand for opioids beyond what was and is reasonable and legitimate use.

23. Defendant Insys, however, went outside of legitimate channels to promote its opioids. It simply paid doctors to prescribe its opioid Subsys, a fentanyl spray approved only for cancer patients, including one prescriber in Rhode Island who in 2017 pleaded guilty to federal kickback and conspiracy charges and was recently sentenced to more than four years in prison. This prescriber, Jerrold Rosenberg, M.D., a physiologist in North Providence received a - hundreds and thousands of dollars over the span of 3 years for promotional talks at high-end restaurants for prescribing the company's products. In some cases, no events actually took place, with Insys sales representatives simply forging signatures of attendees to make the event appear legitimate.

24. Having induced Rosenberg to prescribe Subsys to his patients, Insys also had to

[14] See Accidental Drug Overdose Deaths Occurring in Rhode Island by Month/Year, httpe://wwww.health.ri.gov/data/drugoverdoses/

[15] *See* Theodore J. Cicero, *et al.*, "The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the past 50 Years," *JAMA Psychiatry.* 2014;71(7):821–826.

persuade commercial payors to cover the drug, which they were often reluctant to do given the drug's high cost and approval only for certain types of cancer pain. Insys, upon information and belief at the direction of Kapoor, established an entity called the "Insys Reimbursement Center," which, upon information and belief, passed along false statements to the insurers' prior authorization committees in order to obtain coverage. Insys would obtain patients' confidential medical records by having patients "opt-in" to the reimbursement program, which means they would know these patients were not appropriate Subsys patients. Insys's and Rosenberg's actions cost Rhode Island insurers over $750,000, according to his plea agreement. One patient who testified at his sentence said Rosenberg "made [her] a junkie," and refused to act when she came to him with concerns about addiction.

25. Accordingly, Rhode Island brings this action to hold Defendants accountable for their conduct; and seeks disgorgement, restitution, abatement, damages, and injunctive and equitable relief to redress the harm and halt these unfair, deceptive, and unlawful practices.

## II. PARTIES

A. PLAINTIFF

26. The State is a sovereign state of the United States. Peter F. Neronha is the duly elected Attorney General and is the chief law enforcement officer and attorney for the State. The Attorney General brings this action on behalf of the State in accordance with his statutory and common law authority and pursuant to common law authority.

B. DEFENDANTS

27. 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 general partner of Purdue Pharma, L.P. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. These Defendants are collectively referred to herein as "Purdue."

28. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, Hysingla ER in the United States and in Rhode Island.[16] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 billion and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids. In Rhode Island, from 2006-2014, Purdue accounted for 22% of opioids dispensed by weight and 6% of total dosage units.

29. Rhodes Pharmaceuticals, L.P. is a limited partnership organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Pharmaceuticals L.P. has one general partner, Rhodes Pharmaceuticals, Inc.; and one limited

[16] Purdue has also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

partner, Coventry Technologies L.P., which holds Rhodes Pharmaceuticals, L.P.'s shares. Coventry Technologies L.P. is a Delaware limited partnership with its principal place of business in Stamford, Connecticut. Its general partner is Purdue Pharma Inc. Rhodes Technologies Inc. is a corporation organized under the laws of Delaware with its principal place of business in Coventry, Rhode Island. Rhodes Technologies is a Delaware general partnership with its principal place of business in Coventry, Rhode Island. Rhodes Technologies Inc. is the general partner of Rhodes Technologies and is a subsidiary of Purdue Pharma, L.P. (Rhodes Technologies and Rhodes Pharmaceuticals are collectively referred to as "Rhodes"). Rhodes manufactures and distributes generic opioids, including authorized generic versions of OxyContin and Butrans. Rhodes Technologies also manufacturers the active pharmaceutical ingredient in drugs including Purdue's OxyContin.[17] Among the drug products manufactured by Rhodes is buprenorphine, a drug used to treat opioid dependence. Together, Rhodes and Purdue accounted for 14.4 million opioid prescriptions in the United States in 2016.[18]

30. Richard S. Sackler. M.D. is a resident of Austin, Texas and a board member of Purdue Pharma, L.P. and Rhodes Technologies. Sackler was President of Purdue Pharma from 1999 to 2003 and Co-Chairman in 2003 through 2014. Upon information and belief, Sackler joined Purdue in 1971 as an assistant to his father, Dr. Raymond Sackler. who was then CEO of Purdue. Defendant Sackler served as head of Purdue's Marketing Department and of its Research & Development Departments. From 1995-2003, Defendant Sackler oversaw the launch of OxyContin. Sackler, upon information and belief, has long held an ownership interest in Purdue and Rhodes, and continues to hold such an ownership interest. Through his decisions

[17] At various times, Defendant Mallinckrodt also supplied Purdue with oxycodone.
[18] David Crow, "Billionaire Sackler family owns second opioid drugmaker," *Financial Times,* Sept. 9, 2018 at https://www.ft.com/content/2d21cf1a-b2bc-11e8-99ca-68cf89602132

and directives, Sackler knowingly caused the promotion and sales of Purdue and Rhodes opioids in Rhode Island, from the sales messages passed directly to Rhode Island prescribers by Purdue sales representatives, to the third-party articles and webinars made available to Rhode Island prescribers by Purdue. Sackler is the listed inventor on a number of patents assigned to Purdue or Rhodes, including U.S. Patent 9,3861,628, *Buprenorphine-Wafer for Drug Substitution Therapy* (January 9, 2018), a patent issued, *inter alia*, to Sackler and assigned by Sackler and his co-inventors to Rhodes covering a drug for "drug substitution therapy in drug-dependent human subjects." In other words, having caused the opioid epidemic, Sackler, through his companies, is poised to profit off of its abatement.

31. Insys Therapeutics, Inc.[19] is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys' principal product and source of revenue is Subsys, a transmucosal immediate-release formulation ("TIRF") of fentanyl, contained in a single-dose spray device. Subsys was approved by the Food and Drug Administration ("FDA") solely for the treatment of breakthrough cancer pain. In 2016, Insys made approximately $330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States and in Rhode Island. Several Insys executives and sales managers have been indicted, including sales representatives and regional managers responsible for sales into Rhode Island.

32. John N. Kapoor[20] is a resident of Lake Forest, Illinois, and the former Chairman of Insys. In 2013, *Forbes* Magazine listed him as a billionaire following the success of Insys's initial public offering. In 2017, Kapoor was arrested and charged, along with other Insys

[19] On June 11, 2019, the State voluntarily dismissed all claims asserted against Insys Therapeutics pursuant to Rhode Island Super. R. Civ. P. 41(a)(1)(A).
[20] On June 17, 2019, the State voluntarily dismissed all claims asserted against John N. Kapoor, without prejudice, pursuant to Rhode Island Super. R. Civ. P. 41(a)(1)(A).

executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies by the Office of the United States Attorney for the District of Massachusetts. He at all times personally directed the activities of Insys, including the payment of fraudulent kickbacks to prescribers in Rhode Island, and directed the misrepresentations made to third party payors to obtain off-label coverage of Subsys.

33. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

34. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc. and Teva took over the marketing and promotion of Actiq and Fentora, two TIRF products approved only for breakthrough pain in opioid-tolerant patients with cancer. Teva has promoted its TIRF opioids in Rhode Island, including making payments to 12 different prescribers in Rhode Island, none of whom are oncologists.[21]

35. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States and Rhode Island Teva USA also sells generic opioids in the United States and Rhode Island including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016. Teva is in fact the world's largest maker of generic

[21] Teva also marketed to Jerrold Rosenberg, providing him with food and beverages on 4 separate occasions in 2014 and 2015.

pharmaceutical products."[22]

36. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

37. Defendant Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

38. Defendant Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

39. Defendant Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

40. Defendant Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses

[22] https://www.tevausa.com/Company.aspx

to Teva.

41. Defendant Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

42. Defendant Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide; oxycodone/hydrochloride. Actavis Totowa LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

43. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendants Actavis South Atlantic LLC, Actavis Elizabeth LLC, and Actavis Mid Atlantic LLC, and were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of defendant Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

44. Defendant Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified as a manufacturer or distributor of the morphine sulfate ER drug Kadian on Kadian's label. Actavis Kadian LLC was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

45. Defendant Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt

Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

46. Defendant Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

47. In Rhode Island, from 2006-2014, Teva accounted for 24% of opioids dispensed by weight and 23% of total dosage units, including the Actavis acquired entities.

48. Allergan plc f/k/a Actavis plc, f/k/a Allergan, Inc. ("Allergan plc") is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc.

49. The transaction that created Actavis plc converted each share of Actavis Inc.'s Class A common shares into one Actavis plc Ordinary Share.[23] Actavis Inc. and Actavis plc had the same corporate headquarters both before and after the merger; Actavis plc had the same website as Actavis Inc.; and, Actavis plc maintained all of Actavis Inc.'s officers in the same positions.[24] Actavis plc's SEC filings explained that "references throughout to 'we,' 'our,' 'us,' the 'Company' or 'Actavis' refer interchangeably to Watson Pharmaceuticals, Inc., Actavis, Inc., and Actavis plc depending on the date."[25]

50. Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc. ("Allergan Finance") is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance is a wholly-owned subsidiary of Allergan plc.

51. Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the wholly-owned subsidiary of Allergan plc.

52. Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is a wholly-owned subsidiary of Allergan plc.

53. Allergan manufactures or has manufactured branded and generic opioids, including but not limited to generic versions of Kadian, Duragesic, and Opana in the United States. Allergan manufactures, markets, and sells branded prescription opioids, including Kadian.

54. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was

[23] *See City of Chicago v. Purdue Pharma L.P., et al*. (N.D. Ill. 2015), No. 14-4361, 2015 WL 2208423, at *7.
[24] *See id*.
[25] *See id.*

incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Although it has undergone name changes over time, Mallinckrodt, plc has a long history and describes itself as originally founded by Gustavo Mallinckrodt, Otto Mallinckrodt and Edward Mallinckrodt in 1867. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt Pharmaceuticals has responded to a letter from the FDA concerning Xartemis XR, and the Mallinckrodt Pharmaceuticals logo appears on marketing and/or purportedly educational materials. Mallinckrodt plc was also a signatory to the July 10, 2017 Administrative Memorandum of Agreement with the United States Drug Enforcement Administration outlining its obligations to report suspicious scheduled drug orders. Defendant Mallinckrodt LLC is a Delaware limited liability company with its headquarters in Hazelwood, Missouri. Mallinckrodt manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States, and in Rhode Island. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. Defendant SpecGX LLC, is a wholly owned subsidiary of Mallinckrodt plc and was incorporated in Delaware on November 14, 2016.[26] SpecGX, upon information and belief, currently manufactures and sells in Rhode Island opioids that were previously manufactured by Mallinckrodt LLC.

[26] The State has listed SpecGX as a Defendant for the purpose of ensuring that the State can obtain appropriate injunctive relief.

55. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt discontinued in August 2015. Mallinckrodt promoted its branded opioid products with its own direct sales force.

56. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications. In Rhode Island, from 2006-2014, Mallinckrodt accounted for 22% of opioids dispensed by weight and 42% of total dosage units. According to a report in *60 Minutes*, between 2008 and 2012, Mallinckrodt sold two-thirds of the oxycodone in the State of Florida (or 500 million pills).

57. In 2017, Mallinckrodt entered into a settlement with the United States Drug Enforcement Administration ("DEA") after the DEA's investigation revealed that "Mallinckrodt knew about the diversion [of oxycodone] and sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tablets, placing them into a stream of commerce that

would result in diversion[,]" much of which came from the supply to Florida. Portions of this oversupply were diverted, upon information and belief, to Rhode Island. To settle these claims, Mallinckrodt paid a fine of $35 million.

58. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the United States, with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country and in Rhode Island. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.

59. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson distributes pharmaceutical drugs, including opioids, throughout the country and in Rhode Island. McKesson is incorporated in Delaware and its principal place of business is in San Francisco, California.

60. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids, and for failing to maintain effective controls against diversion at its distribution centers.

61. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country and in Rhode Island. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's is incorporated in Delaware and it

principal place of business is Chesterbrook, Pennsylvania.

62. The Distributor Defendants comprise the "big three" and dominate the wholesale distribution market, including in Rhode Island.

## III. JURISDICTION AND VENUE

63. Subject-matter jurisdiction is authorized by R.I. Gen. Laws § 8-14.

64. This Court has personal jurisdiction over Defendants because Defendants transact business in Rhode Island and/or have the requisite minimum contacts with Rhode Island necessary to constitutionally permit the Court to exercise jurisdiction, with such jurisdiction also being proper under Rhode Island's long arm rule. Super.R.Civ.P. 4. Among other business activities in Rhode Island, the Manufacturing Defendants have employed people in Rhode Island to visit Rhode Island doctors in their Rhode Island offices for the purpose of delivering marketing messages and encouraging such doctors to write prescriptions for Manufacturing Defendants' products. The Distributor Defendants transact business in Rhode Island by selling the Manufacturer Defendants' opioids to retail pharmacies located in Rhode Island.

65. Rhode Island has general jurisdiction over the Rhodes Defendants as their principal place of business is in Rhode Island.

66. This Court has personal jurisdiction over Defendant Sackler because he personally directed Purdue to conduct the deceptive or unfair acts or practices alleged herein that took place and caused harm in Rhode Island and/or because he has the requisite minimum contacts with Rhode Island necessary to permit this court to exercise jurisdiction. Business activities that Sackler directed include Purdue's employment of a substantial number of sales representatives nationwide, including in Rhode Island, to visit doctors in their local offices for the purpose of delivering marketing messages and encouraging such doctors to write prescriptions for Purdue's opioid products. Consequently, Purdue's opioids are prescribed

throughout Rhode Island by prescribers who have been exposed to Purdue's deceptive marketing, and with Sackler's knowledge and subject to his control, Purdue has caused its opioids to be distributed throughout Rhode Island and ultimately taken by consumers in Rhode Island. In addition, he personally has transacted business in Rhode Island relating to the subject matter of this lawsuit by directing the operations of Defendant Rhodes; and by assigning patents to Defendant Rhodes, including U.S. Patent No. 9,3861,628, *Buprenorphine-Wafer for Drug Substitution Therapy*.

67. This Court has personal jurisdiction over Defendant Kapoor because he personally directed the commission of tortious acts in Rhode Island, including payments to Jerrold Rosenberg to induce him to prescribe Subsys.

68. Venue is proper in this Court pursuant to R.I. Gen. Laws § 8-2-27.

## IV. PURDUE ILLEGALLY MISREPRESENTED THE RISKS AND BENEFITS OF ITS OPIOIDS

69. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which required long-term use of the drugs at increasingly high doses as patients developed tolerance. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, and at Sackler's direction, Purdue has sought—with a marketing campaign that was as successful as it was deceptive—to turn that consensus on its head, primarily by denying, distorting, or failing to disclose the risk of addiction and overstating the benefits of using opioids long-term. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Purdue not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients

with chronic pain conditions and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions.

70. Before Sackler directed Purdue's launch of OxyContin in 1996, opioids were widely recognized as highly addictive, and therefore suitable only for severe pain and short-term use. There was no evidence that opioids were appropriate or could be used safely on a long-term, outpatient basis.

71. However, the market for actue pain and end-of-life pain was relatively small. Thus, when Purdue launched OxyContin, it sought to broaden its use to chronic pain such as lower back pain, arthritis, and headaches. These conditions are more prevalent, and they last longer, providing Purdue with more prescriptions per patient and, thus, sustained revenue.

72. A successful launch of OxyContin was particularly important to Sackler because he knew there would soon be generic competition for its morphine extended release drug, MS Contin. In fact, Sackler was aggressive about finding other applications for the "Contin" extended release technology when he and Purdue came up with the idea of applying it to oxycodone, an older drug used in short-acting opioids like Percocet.

73. Thus, Purdue's deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and required opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

## A. PURDUE FALSLEY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

74. Purdue has relied heavily on their sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Purdue made more visits to more Rhode Island prescribers than any other opioid maker, based on publicly-available data

from the Center for Medicare and Medicaid Services. Defendant Sackler testified that sales representatives were the main way that Purdue promoted its opioids, and that regular visits from the sales force was the best way to induce prescribers to start prescribing Purdue's opioids and to keep doing so.

75. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[27] The Report quotes *ProPublica* findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

76. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturing Defendants directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each visit. Call notes are kept and submitted by sales representatives to reflect their interactions during sales visits.) They relied upon prescriber-identifiable data, as well, to target the largest prescribers of their products. Sales representatives also had incentives to promote their products aggressively, as their compensation was based on prescriptions, not how well they informed prescribers of the true qualities of their drugs.[28] These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and

[27] Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.

[28] Although sales representatives are typically compensated based on sales of their company's branded products, Purdue compensated its sales representatives based on the volume of OxyContin as well as Rhodes's authorized generic versions. Thus, Rhodes's authorized generic fills can be attributed to Purdue's marketing of OxyContin, as well as to Purdue's promotion of opioids as a class through its unbranded marketing.

supplied by the companies and forbade them to use promotional materials not approved by the company's marketing and compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief, their sales forces in Rhode Island carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country. [29]

77. Purdue was aware of the strength of its in-person marketing. The effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls.[30] A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals restricted sales representatives' access to prescribers.[31] Another study compared different marketing strategies and found that sales representatives have the strongest effect on driving drug utilization—even more than drug pricing.[32] Doctor meetings with sales representatives have also been found to be related to changes in doctors' prescribing practices and requests to add the drugs to their hospitals' formularies.[33] In short, Purdue's sales staff making "detail visits" had the most powerful effect on prescriptions, and contact with sales representatives is the most consistent predictor of

[29] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Rhode Island in the same manner as elsewhere.
[30] Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 Am. J. Pub. Health 221–227 (2009).
[31] Ian Larkin *et al*., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing, 317 J. Am. Med. Ass'n 1785 (2017).
[32] Berdent ER, *et al*. Information, marketing and pricing in the US antiulcer drug market. Amer Econ Rev 1995, 85:101-105.
[33] *Id.* citing Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? JAMA 2000,283:373-80.

physicians' adoption of new products. One reason for their efficacy is that prescribers are often unaware that sales representatives' visits change their prescribing.

78. Purdue also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

79. By 2000, Purdue had approximately 94,000 doctors on its physician call list. Purdue also recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with "educational" programing and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002, including, upon information and belief, programs attended by Rhode Island prescribers.

80. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation ("APF")

and the American Pain Society ("APS"), that were also able to exert greater influence because of their seeming independence. Purdue exerted influence over these groups by providing major funding directly to them, as well. According to data collected by the Senate Finance Committee, Purdue gave over $4 million to several of these organizations over the last five years alone.[34] These organizations appeared to be neutral and independent, but in reality were used by drug companies to disseminate promotional messages, rendering them "front groups" for the opioid industry. These entities put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. Purdue distributed these publications to Rhode Island prescribers or posted them on its website.

81. The advantage to a drug company of working with and through front groups is that the FDA does not regulate marketing funneled through third-parties or unbranded communications that do not describe specific products, directly or indirectly.

82. Purdue used its sales force and allied front groups to falsely promote its opioids as safe and effect to Rhode Island prescribers, as follows.

*I. Purdue Minimized and Mischaracterized The Risk of Addiction.*

83. To convince prescribers and patients that opioids are safe, Purdue deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, (3) all other patients could

[34] Shortly it received a Senate Finance Subpoena in 2012, APF shut its doors citing "irreparable economic circumstances." Upon information and belief, legislative scrutiny caused its pharmaceutical company donors to stop considering APF useful.

safely be prescribed opioids, and (4) even high-risk patients could be prescribed opioids if closely managed.

84. Purdue deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to Purdue, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. One Rhode Island prescriber attended a Purdue-sponsored talk where the speaker said patients in true pain would not become addicted to opioids. Another internist in Lincoln reported that he felt that addiction risks were reduced in elderly patients, a misrepresentation Purdue did not correct. Purdue discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain. Upon information and belief, based on the uniformity of Purdue's practices, the same message was delivered to prescribers in Rhode Island. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction.

85. Purdue's sales representatives also failed to disclose to prescribers nationally, and upon information and belief, in the Rhode Island the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

86. Purdue falsely portrayed "true" addiction in its narrowest form. Purdue's earliest marketing included claims that the risk of addiction was less than 1%, a claim that appeared in

educational pamphlets and educational videos Purdue disseminated.[35] (Tragically, one of the patients who appeared in the video claiming OxyContin did not "make him groggy" subsequently became addicted and died in a car accident after he blacked out.[36]) This claim that opioids were rarely addictive was purportedly based on a letter to the editor of the *New England Journal of Medicine* that relied on observation of notations in patient charts of hospital inpatients, not a systematic study.[37]

87. Providing *Relief, Preventing Abuse*, a pamphlet it published in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

88. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including those in Rhode Island.

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[35] One video made by Purdue in 1998 entitled "I got my life back" is available online and features a physician testimonial stating the addiction rate is among pain patients who were treated by doctors is "much less than 1%" and opioids "should be used much more than they are for patients in pain." *See* https://www.youtube.com/watch?v=Er78Dj5hyeI

[36] Patrick Radden Keefe, "The Family That Built An Empire Of Pain," *New Yorker* (October 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain

[37] J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302(2) *New Eng. J. Med.* 123 (1980). Because it was a 1980 study, standards of care almost certainly would have limited opioids to acute or end-of-life situations, not chronic pain.

89. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation. Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill. Purdue's and APF's alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a "Master Consulting Services" Agreement on September 14, 2011. That agreement gave Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

90. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction.

91. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the

Purdue copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[38]

92. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.[39]

93. Purdue's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence.

### *II. Purdue Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond to Aberrant Behavior by Prescribing More Opioids*

94. Purdue deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

95. Purdue, through its unbranded imprint *Partners Against Pain*[40], promoted

[38] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).
[39] Id.
[40] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns

pseudoaddiction through at least 2013 on its website, including by disseminating the American Pain Society's "Definitions Related to the Use of Opioids for the Treatment of Pain: "Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated."

96. Mallinckrodt's efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. As explained above, studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. Addiction can result from the use of any opioid, "even at recommended dose"[41] and the risk increases with chronic (more than three months) use.

97. The Federation of State Medical Boards ("FSMB"), a trade organization representing Rhode Island's state medical board as well as others, finances opioid- and pain-specific programs through grants from Purdue. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

98. *Responsible Opioid Prescribing* was sponsored by Purdue. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers

about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

[41] FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics, FDA (Sept. 10, 2013); see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death, FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

of opioid medications." In all, more than 6,000 copies of *Responsible Opioid Prescribing* were distributed in Rhode Island.

99. Another publication, APF's *A Policymaker's Guide* (2011) claimed, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided substantial funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to Rhode Island prescribers online.[42]

100. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book includes a discussion of the concept of pseudoaddiction.

101. Purdue also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for Purdue and other opioid makers. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

102. The CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]patients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[43] and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the

[42] *See* American Pain Foundation., *A Policymaker's Guide to Understanding Pain & Its Management* (2011), https://www.documentcloud.org/documents/277603-apf-policymakers-guide (last visited April 4, 2018).
[43] CDC Guideline at 13.

patient is "not receiving a clear benefit."[44]

103. Within Rhode Island, Purdue's sales representatives repeatedly promoted the baseless and misleading concept of pseudoaddiction. For example, after a luncheon with anesthesiology office staff in Providence, a Purdue representative reported the staff had not considered pseudoaddiction to be a distinct concept until told of it by the sales representative. At another event where the sales representatives talked about pseudoaddiction, the representative described the prescriber's reaction as "eye opening." As described below, prescribers who have received this misrepresentation subsequently wrote prescriptions that were paid for by Rhode Island's Medical Assistance Program.

*III. Overstated the Efficacy of Screening Tools*

104. Purdue falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants, advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Purdue undermined general concerns or warnings regarding addiction by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

105. Such misrepresentations regarding the ability to safely prescribe opioids without the risk of addiction made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Purdue aimed them at general practitioners

[44] *Id.* at 25.

and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

106. Purdue conveyed these "safe prescribing" messages through their in-person sales calls to doctors. For example, Purdue sales representatives in Rhode Island also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

107. Purdue also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to Rhode Island prescribers.

108. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

109. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, using screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

110. Purdue used its involvement in the College on the Problems of Drug Dependence

("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids without addicting patients. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Rhode Island, attended these conferences.

111. Purdue's efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

112. Further, the CDC Guideline confirms the falsity of Purdue's claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[45]

113. When one Wakefield urologist asked his sales representatives for information about screening tools in 2009, he was given a copy of *Providing Relief, Preventing Abuse*, which

[45] CDC Guideline at 28 (emphasis added).

contained inaccurate information about pseudoaddiction, as discussed above. In numerous other sales visits in Rhode Island, Purdue sales representatives encouraged the use of patient contracts. Purdue's call notes in Rhode Island illustrate the difficulty of reliably identifying at-risk patients. A 2009 call note reflecting a visit with a Providence physician assistant noted that a patient, an ex-military service-member, who had been taking OxyContin without any signs of abuse, was discovered by a local pharmacy to be receiving multiple prescriptions. An internist in Lincoln reported an older patient who had overdosed from crushing OxyContin mixed with a benzodiazepine had been treated for years without incident. The prescribers had not identified that either of these patients was struggling with addiction or abuse.

114. The history of OxyContin's seventeen different labels shows a gradual and seemingly grudging acknowledgement of risks that should have been disclosed sooner. It was only in 2014, and only then in response to a citizen petition Purdue and its front group proxies opposed, that language appeared in the box label to warn that OxyContin, Hysingla ER, MS Contin, and other extended release opioids "exposes patients and other uses to the risks of opioid addiction, abuse and misuse, which can lead to overdose or death" and also removed language that "risk for opioid abuse is increased in patients with a personal or family history of substance abuse," in order to avoid giving prescribers a false sense of security. Prior to that, Purdue's labels only warned about the risk of criminal abuse and diversion, consistent with and furthering the false narrative that opioid addiction was a problem of illicit use, and not the overuse, of opioids.

115. Yet Purdue was certainly aware from information solicited through its sales visits and post-marketing surveillance that its opioids were resulting in widespread addiction, abuse, and overdose. Drug companies collect information form several different post-marketing

surveillance vendors, including the Drug Abuse Warning Network (DAWN), the National Household Survey on Drug Use and Health (NSDUH), the Researched Abuse, Diversion and Addiction Related Surveillance program (RADARS), and National Addictions Vigilance Intervention and Prevention (NAVIPPRO). Purdue, in fact, contracted with NAVIPPRO and RADARS to conduct studies of the impact of ADF OxyContin on abuse in particular areas and to measure calls to poison control centers for overdoses. Purdue also has hotlines and websites for prescribers, patients, or caregivers to report adverse events, like overdoses and addiction. Purdue regularly checks the FDA's MEDWATCH database as part of its ongoing post-marketing surveillance requirements and obligations to update their labels, discussed above. Purdue's website represents as follows:

> Purdue Pharma routinely collects and analyzes safety information on our products, including reports from healthcare professionals and patients about adverse events and product complaints. We submit safety reports as appropriate to the U.S. Food and Drug Administration (FDA), which reviews these reports and, when necessary, takes steps to alert healthcare professionals of emerging safety concerns.[46]

116. Thus, Purdue at all times knew that its and other opioids were resulting in medically-caused addiction much sooner than other stakeholders, yet did not take necessary steps to ameliorate it.

## B. PURDUE OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE

### *1. Purdue Mischaracterized the Benefits and Evidence for Long-Term Use*

117. To convince prescribers and patients that opioids should be used to treat chronic pain, Purdue had to persuade them of a significant upside to long-term opioid use. Assessing

[46] http://www.purduepharma.com/healthcare-professionals/ask-purdue-medical/report-adverse-event/

existing evidence, the CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[47] In fact, the CDC found that "[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 ≤ 6 weeks in duration)"[48] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[49] The FDA also determined that opioid use disorder and overdose risk are present when opioids are taken as prescribed.[50] As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

118. Purdue touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. Going back to OxyContin's launch, Purdue promoted it as improving patient function through materials like fishing hats and compact discs of big band music called "Get in the Swing with OxyContin."

119. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Purdue. Upon information and belief, Purdue exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic

[47] *Id.* at 10.
[48] *Id.* at 9.
[49] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).
[50] Id.

pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

120. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Purdue in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, and a majority received support from at least one other opioid manufacturer.

121. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. 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 Guidelines were influenced by contributions that drug companies, including Purdue, made to the sponsoring organizations and committee members.

122. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of

a low risk of addiction.

123. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

124. Purdue also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results … should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[51] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[52] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

[51] Jacques R. Caldwell, *et al*., Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial, 266.4 Journal of Rheumatology 862-869 (1999).
[52] *Id*.

125. Call notes reflect that Purdue sales representatives encouraged the use of its opioids for chronic pain patients in Rhode Island sales visits. In at least one instance, Purdue sales representatives noted reviewing patients' medical charts to help identify appropriate patients for OxyContin. Upon information and belief, Purdue would have identified patients who were on short-acting or immediate release opioids and did not need around-the-clock opioids, and this practice raises significant privacy considerations. Another prescriber stated that sales representatives never disclosed the lack of evidence for long term use.

*2. Purdue Overstated Opioids' Effect on Patients' Function and Quality of Life*

126. Purdue also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Purdue-sponsored materials that, upon information and belief, were distributed or made available in Rhode Island, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

127. *Responsible Opioid Prescribing* (2007), sponsored and distributed in part by Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

128. 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." The guide was available online until APF shut its doors in May 2012.

129. Likewise, Purdue's claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

130. One pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[53] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

131. The CDC Guideline notes that "there is no good evidence that opioids improve

[53] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse*?*

pain or function with long-term use."[54] The FDA and other federal agencies have made this clear for years.[55] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[56] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[57] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[58]

132. In materials Purdue produced, sponsored, or controlled, Purdue omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

133. In Rhode Island, however, sales representatives continued to promote opioids as safe and effective. One Rhode Island doctor described improved function as "often the message"

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[54] *Id.* at 20.

[55] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] 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."). The FDA's warning letters were available to Defendants on the FDA website.

[56] CDC Guideline at 2.

[57] *Id* at 18.

[58] *See* n. 7, *supra*.

and "quality of life" was often used.

*3. Purdue Omitted and Mischaracterized Adverse Effects of Opioids*

134. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression. Purdue routinely ignored the risks of hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[59] in which the patient becomes more sensitive to pain over time, hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms). Despite these risks, in 2014, a sales representative urged a Pawtucket internist to remember that OxyContin was well tolerated in patients over 65, despite to the special risks of opioids to elderly patients. Purdue also learned from its sales visits that Rhode Island prescribers were prescribing OxyContin to Iraq and Afghanistan veterans without discussions of the higher risks of co-morbid conditions or drug interactions faced by veterans, many of whom were taking concurrent anti-anxiety medications, for instance, that substantially increase the risk of overdose when taken with opioids.

135. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is

[59] Id.

approximately 3,200, far fewer than from opioids).[60] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

136. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

137. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

138. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[61]

139. Again, Purdue's misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

### *IV. Purdue Told Doctors That Opioids Could be Taken in Ever Higher Doses Without Disclosing Their Greater Risks*

140. Purdue falsely claimed to prescribers and consumers that opioids could be taken

[60] The higher figure reflects deaths from all causes.
[61] Meredith Noble M, *et al*., *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010.).

in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice a day, despite knowing that OxyContin frequently did not provide 12 hours of relief to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

141. Purdue-sponsored publications and CMEs available, upon information and belief, in Rhode Island also misleadingly suggested that higher opioid doses carried no added risk.

142. Through at least June 2015, Purdue's *In the Face of Pain* website promoted that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would. Though at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

143. A Policymaker's Guide, the 2011 publication on which, upon information and belief Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids, nor the significant hardships that often accompany cessation of high-dose opioids. This publication is still available online.62

144. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater

[62] *See* n. 42, *supra*.

than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses.[63] As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[64] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[65]

145. Purdue was well aware that prescribers in Rhode Island dispensed high dose opioids from reports in call notes. At one 2007 luncheon, a prescriber reported having "success" prescribing a patient with 960 mg of OxyContin per day–the equivalent of 1,440 mg MED–a sum that necessitates 12 of the highest dose pills per day (and far more than the presumptive limit of 90 mg MED recommended by the CDC). It also takes longer to wean patients off high dose opioids, increasing the risk that patients will be "stuck" on the drugs, but increasing the revenue to manufacturers like Purdue. In fact, one of highest prescribers of opioids in Rhode Island continues prescribing to patients in an effort to gradually lower doses from high peaks.

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[63] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152(2) Annals of Internal Med. 85-92 (Jan. 19, 2010). Most overdoses were medically serious and 12% were fatal.

[64] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[65] CDC Guideline at 16.

146. The average OxyContin prescription paid for by Rhode Island's Medical Assistance Program exceeded 90 mg of MED.

### C. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT

147. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

148. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed to prescribers that the solution to end of dose failure is not more frequent dosing but higher doses—which pose greater risks.

149. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Yet it was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing.

150. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar. While the OxyContin label indicates that "[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours," Purdue has conducted no such studies.

151. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never

approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

152. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

153. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[66] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

154. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue

[66] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage." Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made repeatedly in Rhode Island by sales representatives in their visits with prescribers. Purdue sales representatives also promoted OxyContin to doctors as better alternative to shorter acting opioids, regardless of whether or not the short acting drugs were adequately treating pain or that an around-the-clock treatment was necessary. This is problematic because of heightened risks of overdose associated with extended release opioids that prompted the FDA to clarify their indication in 2013 to be appropriate not just for pain lasting for an extended period of time, but pain requiring continuous analgesia. One prescriber told by Purdue that Purdue's extended release opioid was preferable to short-acting drugs in July 2007 then wrote 88 prescriptions for OxyContin covered by Rhode Island Medical Assistance Program, incurring $66,402.32 in charges.

155. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more dangerous higher dosing, rather than increased frequency of use, regardless of any marketing

advantage.[67]

156. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[68]

157. There are numerous examples of Purdue promoting its opioids for 12 hours in Rhode Island, despite knowing that the drugs often did not last 12 hours. One call note from a Purdue sales representative from a 2010 visit to a Providence physician assistant reported the prescriber told the representative "most of the [patients] that she has on OxyContin need to take it … every 8 [hours]." The representative reported giving her information, including "titration," which signifies instructions on how to increase the dose. Purdue sales representatives also old one prescriber in Woonsocket that patients on short-acting opioids were more likely to experience pseudoaddiction, implying Purdue's longer-acting formulation were safer.

### D. PURDUE OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS

158. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Purdue seized them as a market opportunity. These

[67] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.
[68] CDC Guideline at 16.

companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's false and misleading marketing of the benefits of its ADF opioids preserved and expanded its sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids – and thereby prolonged the opioid epidemic in Rhode Island.

159. Reformulated ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

160. It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

161. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. In particular, Purdue sought to promote ADF opioids as "safer" than other opioids and would reduce opioid abuse overall. One Rhode Island prescriber,

for example, reported that he was told OxyContin "couldn't be tampered with" and that "people couldn't misuse it." This claim is inconsistent with data Purdue itself submitted to the FDA that would show that only 2.2% of deaths from OxyContin overdose could be traced to injection or snorting—facts Purdue did not, upon information and belief, disclose to prescribers. These omissions provided a false sense of security to prescribers, who would in turn prescribe more expensive, branded OxyContin in the belief it was safer than alternatives, and would be more comfortable prescribing opioids generally.

162. Misleading statements and omissions by Purdue about the relative safety of ADF drugs were also inconsistent with the FDA-approved labels for Purdue's ADF opioids. Approved labeling acknowledges that that abusers seek opioids because of their high likeability when snorted or injected, that their abuse deterrent properties can be defeated, and that they can be abused orally by simply taking more pills. The labels, more importantly, do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

163. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[69] and is still regularly tampered with and abused. A critical care assistant in Woonsocket told a Purdue representative in 2010 that his patients told him instructions on how to abuse reformulated OxyContin were online. Websites and message boards used by drug abusers, such as bluelight.org and reddit, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's

[69] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected.

164. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin and fentanyl.[70]

165. A 2013 article presented by Purdue employees based on review of data from poison control centers, while concluding that ADF OxyContin can reduce abuse, ignored important negative findings. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

166. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[71] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF

[70] A National Academy of Sciences report cites evidence that up to 80% of the increase in heroin use following the reformulation could be attributed to the reformulation, and this risk was higher in areas, like Rhode Island, that already had persistently high rates of opioid misuse. National Academy of Sciences, *Pain Management and The Opioid Epidemic, Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, Bonnie, Ford, Phillips, *et al*., Washington D.C. (2017) at 192.

[71] CDC Guideline at 22. (emphasis added).

opioids] actually reduce rates of addiction, overdoses, or death." [72]

167. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[73] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

168. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

169. Nevertheless, Purdue's marketing influenced prescribing. For instance, a Cranston internist told Purdue sales representatives that she prescribes OxyContin because she likes the abuse-deterrent labeling. A Providence County pharmacy technician told a Purdue sales representative that she saw the draw of abuse-deterrent formulations in increased Hysingla ER prescribing. A pharmacist in Cumberland also overcame initial resistance to stocking Hysingla ER once the ADF properties were explained. An East Greenwich prescriber also told Purdue he

[72] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.
[73] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

"liked" the ADF properties. A Pawtucket pharmacist told Purdue the ADF properties gave her "peace of mind." A Woonsocket neurologist who told Purdue's sales representative he was not starting new patients on opioids indicated a willingness to consider reformulated OxyContin, agreeing the supposed ADF properties would be "important" to him in new patient starts. The marketing and sales presentations such as these resulted in OxyContin prescriptions being written and covered by Rhode Island's Medical Assistance Program.

170. Sales representatives told a Pawtucket internist in 2015 that patients she sees who are worried about abuse, such as those who call in early refills, might be "perfect" candidates for OxyContin or Hysingla ER. Purdue also told a Pawtucket rheumatologist that ADF OxyContin should help overcome reluctance to prescribe opioids. Purdue sales representatives in numerous cases encouraged the use of ADF opioids in response to state prescribing guidelines issued in March 2015 (updated again in February 2017),[74] in the belief that ADF opioids satisfied the policy of safe and appropriate opioid prescribing.

### E. DEFENDANT SACKLER APPROVED PURDUE'S DECEPTIVE MARKETING THROUGHOUT THE RELEVANT TIME PERIOD

171. In his capacity as President of Purdue during the launch of OxyContin, and as a board member after 2003 who was personally active in directing Purdue's operations, Sackler knew of and approved deceptive marketing tactics. As a member of the boards of relevant Purdue and Rhodes entities, Sackler oversaw the hiring of sales representatives, the number of visits made, and the choice of drugs to promote. On at least one occasion, Sackler acted as a sales representative himself, e-mailing a prominent cardiologist and popular author of self-help books that OxyContin tablets were "easy to use" and that there was no "right dose," falsely

[74] *See* Rules and Regulations for Pain Management, Controlled Substance Prescribing and the Registration of Distributors of Controlled Substances in Rhode Island, http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/8473.pdf

suggesting that the doses could be increased indefinitely without added risk to the patient.

172. Defendant Sackler was also aware of specific examples of deceptive marketing through receipt of call note reviews in his capacity as a board member, in 2010 and 2011, and on information and belief, at all times relevant to this action. As President, Sackler received reports of opioid overdoses and reports of misuse and abuse. He also continued to be involved in the operations of Purdue as he and other members of the board (including his brother, cousin, and nephew) formed a committee to discuss patent licenses in 2013.

173. Sackler also personally directed a deceptive strategy to misrepresent the strength of OxyContin. At the time of launch, owing to the use of oxycodone in short-acting combination drugs, it had the reputation as a "weak" drug, even though it is 1.5 times stronger than morphine on a milligram to milligram basis. Sackler personally sought to exploit this perception, which he knew was false in order to position OxyContin as a drug to be used earlier in the treatment of pain than morphine. In deposition testimony, Sackler referred to this as oxycodone's "personality," in that it lacked the association in the prescriber's mind morphine had as a drug reserved for end-of-life and most severe pain. At the same time, Purdue, at Sackler's direction, set the price for OxyContin based on a formula treating OxyContin as *twice* as strong than morphine. Sackler understood that by starting patients on OxyContin, they would rather keep increasing its dose than switch to morphine—an especially profitable outcome for Purdue.

174. Sackler, as a member of the family that owns Purdue personally benefitted from the success of OxyContin. At various points, he as a director approved the distribution of funds from Purdue to shareholders, including himself and his extended family, including in investment funds managed by Sackler's grandson David, also a Purdue board member.

175. In addition to knowingly minimizing the risk of addiction, Defendant Sackler

allowed Purdue to be willfully blind to evidence of opioid abuse. When asked in a 2015 deposition if it would have been a good idea before putting OxyContin on the market to have an abuse monitoring system and database from which to tell if the drug was being diverted or abused, Defendant Sackler acknowledged, "Absolutely, yes." Despite knowing that such surveillance was appropriate, given the dangerous nature of OxyContin, Defendant Sackler did not direct Purdue to implement such a system at launch and, upon information and belief, Purdue did not do so for many years thereafter.

176. In a deposition taken for prior litigation, a Purdue legal secretary named Maureen Sara testified that in late 1999, she sent a memorandum to the Sacklers, including Defendant Sackler, about what she had learned on the internet about "crushing the tablets [of OxyContin], taking the coating off, cooking it up. Shooting or snorting it."

177. Sackler also received adverse event reports that made clear to him that patients were becoming addicted to, abusing, overdosing on, and dying from OxyContin. Between 2000 and 2002, for example, adverse event reports circulated to Sackler included reports of abuse, addiction, withdrawal, overdoses, and deaths from OxyContin, such as:

| | | |
|---|---|---|
| 3/11/2002 | OxyContin Tablets 10mg | A 31-year old male experienced "hardcore" addiction while reportedly taking OxyContin (controlled release oxycodone hydrochloride. The media in the USA reported this case. |
| 4/9/2002 | OxyContin Tablets 80mg | A female patient experienced withdrawal symptoms, chills and shakes . . . while on OxyContin. |
| 4/22/2002 | OxyContin Tablets | Female patient died suddenly . . . brought about and exacerbated by OxyContin intoxication while taking OxyContin . . . for myofascial pain syndrome and unspecified lower back pain." |
| 5/13/2002 | OxyContin Tablets | Female patient addicted to OxyContin and suffering withdrawal symptoms, drug addiction, physical injury, emotional distress |
| 6/3/2002 | OxyContin Tablets 80mg | Via Purdue IPAP [Individual Patient Assistant program]: "40-year-old white female patient experienced drug abuse while taking OxyContin 80 mg q8hours for non-malignant pain… patient was abusing OxyContin and . . . drug seeking behavior |

| | | |
|---|---|---|
| 6/28/2002 | OxyContin Tablets (plus 4 other preparations) | 34-year-old male patient experienced drug addiction and died from a drug overdose while taking OxyContin and other unspecified drugs. |
| 1/09/2003 | OxyContin Tablets 10 mg<br>OxyContin Tablets 20 mg<br>OxyContin<br>Tablets 80 mg | Male patient experienced drug addiction and withdrawal while taking OxyContin for "bad back" after going from 20 to 160 mg doses a day as prescribed |

178. From at least 1999, Defendant Sackler was personally aware that: (1) OxyContin was being prescribed without proper care; (2) OxyContin was widely abused, including orally, and not just through snorting or injecting; (3) Purdue failed to adequately disclose the risks of abuse and diversion; and (4) as noted above, OxyContin was wrongly, and dangerously, perceived as safer than morphine.

179. According to Barry Meier's book *Pain Killer*, in early 2001, Purdue met with the DEA, which was starting to raise alarms over OxyContin overdoses. Defendant Sackler participated in this meeting and defended OxyContin as an extremely good drug. According to the book, the head of the DEA's Office of Diversion Control leaned across to Defendant Sackler and stated: "People are dying. Do you understand that?" Based on Purdue's continued marketing conduct, Sackler either did not understand or care, for Purdue did nothing to rein in Purdue's misleading promotion of OxyContin.

180. Reinforcing the DEA's message, in February 2001, Defendant Sackler was among a group of Purdue officials who received an Issues Monitoring Report that included reports of OxyContin abuse in different areas of the country.

181. In May 2001, Defendant Richard Sackler was among a small group of Purdue officers briefed on a meeting between senior Purdue and FDA officials on April 23, 2001 regarding OxyContin. FDA's stated purpose in the meeting was to "provide comments and suggestions on a Risk Management program for OxyContin." While the FDA reported that it

was looking at all opioids, Purdue's summary of the meeting, which was shared with Defendant Sackler, recounted that the FDA was focused on OxyContin as "'**it is the bad actor**.'" (emphasis added). Purdue promised that it was "taking this problem very seriously" and shared FDA's "concern regarding the misuse and abuse of our product . . ." The FDA reported that data showed, since 1995, OxyContin prescribing had shifted from oncology to family practitioners and from cancer to chronic conditions like lumbago, myalgia, and "other back pain related terms" and that OxyContin prescribing "had increased 10 fold." Purdue confirmed that this data was consistent with other data it had.

182. Dr. Sharon Hertz of the FDA's Division of Anesthetic, Critical Care & Addiction Drug Products requested that OxyContin's package insert be revised with "knowledge gained from the experience with the product on the market added to the abuse and adverse event section of the insert" and "improvements throughout the drug abuse section." Dr. Cynthia McCormick, the Division Director noted that it is the perception of OxyContin is that "it is good for whatever ails you" and that needs to be changed. Dr. Hertz added that "doctors did not have the right perception about the use of OxyContin. The implication was that the prescribing behavior is too casual, 'this is not a big deal.'" Purdue had, and continued to cultivate this perception for roughly two decades.

183. Purdue acknowledged that it was aware of abuse of OxyContin orally (without tampering), as well as by snorting or injecting. It was not, the FDA explained, a matter of changing a few words in OxyContin's label; Dr. McCormick declared that "'**major overhaul is my message**'. The prescribing of OxyContin is creeping into a whole population of people where it doesn't belong. Just rewriting the abuse and dependence section won't help much**,** that part of the insert is not a pivot point" (emphasis added). Another FDA participant asked that

Purdue "refocus our promotional materials and make the risks of abuse and diversion more prominent."

184. In 2001, Purdue revised the indication and warnings for OxyContin and withdrew the 160 mg strength of OxyContin, but, as would have been obvious to Defendant Sackler, did not go nearly as far as the FDA recommended or the known risks of the product demanded.

## V. INSYS EMPLOYED FRADULENT, ILLEGAL, AND MISLEADING MARKETING SCHEMES TO PROMOTE SUBSYS

185. Insys' opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

186. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Teva's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" and to "ensure safe use and access to these drugs for patients who need them."[75] Prescribers must enroll in TIRF REMS before writing a prescription for Subsys.

187. As part of the TIRF REMS program, all prescribers interested in prescribing Subsys were required to acknowledge they "understand that TIRF medicines are indicated only

[75] Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, December 29, 2011.

for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain."[76] Further, the form required the prescriber to indicate that he or she "understand[s] that TIRM medications are contraindicated for use in opioid non-tolerant patients" and that "TIRM medicines must not be used to treat any contraindicated conditions … such as acute or postoperative pain, including headache/migraine."[77]

188. Since its launch, Subsys has been an extremely expensive medication, and Insys has increased its prices every year. Depending on a patient's dosage and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

189. Due to its high cost, in most instances prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied … meaning no reimbursement would be due."[78]

190. These prior authorization requirements proved to be daunting. Subsys received

[76] https://www.tirfremsaccess.com/TirfUI/rems/pdf/prescriber-enrollment-form.pdf
[77] *Id*.
[78] Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.

reimbursement approval in only approximately 30% of submitted claims.[79] In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (IRC) to obtain approval for Subsys reimbursements.[80] This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients' diagnoses and medical conditions.[81] This practice occurred on a nationwide and corporate level, and upon information and belief, based on criminal indictments brought against prescribers and executives, at least one Rhode Island prescriber falsified patient records and did so with Insys's knowledge in order to obtain insurance coverage for Subsys.

191. Subsys has proved to be very profitable for Insys. Insys made approximately $330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.[82]

192. Since its launch in 2012, Insys has aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresented the appropriateness of Subsys for treating those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speaker programs in exchange for prescribing Subsys. And it defrauded insurance providers and health benefit payors into paying

[79] German Lopez, Want to Understand How Big Pharma Helped Create the Opioid Epidemic? Read This Report, Vox, September 6, 2017.
[80] Staff Report, Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.
[81] German Lopez, Want to Understand How Big Pharma Helped Create the Opioid Epidemic? Read This Report, Vox, September 6, 2017.
[82] *Id*.

for improper prescriptions of Subsys. These fraudulent and misleading schemes had the effect of pushing Insys' highly potent and dangerous opioid onto patients who did not need it, further exacerbating the opioid epidemic.[83]

193. In addition, Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard.[84] The compensation structure was heavily weighted towards commissions, and rewarded reps more for selling higher (and more expensive) doses of Subsys, a "highly unusual" practice because most companies consider dosing a patient-specific decision that should be made by a doctor.[85]

194. The Insys "speakers program" was perhaps its most widespread and damaging scheme. In Rhode Island, the program relied on one prescriber, Jerrold Rosenberg, in particular. Rosenberg received nearly $200,000 from Insys, representing 94% of Insys's promotional spending in the state. Rosenberg was paid $178,740 for 85 talks, although only 59 events reported any attendees—thus indicating that these were not paid-for promotional events, but rewards to Rosenberg for his own prescribing. Rosenberg received between $1,600 and $4,800 for each "talk." Another event in 2013 in Rhode Island was given by a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, who in 2015 plead guilty to receiving $83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. In her guilty plea, the nurse admitted that she was

[83] *Id*.
[84] Katie Thomas, Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller, New York Times, May 13, 2014.
[85] Id.

receiving the speaker fees in exchange for writing prescriptions for Subsys.[86]

195. Senior executives, including Kapoor, closely tracked the impact the kickbacks had on the prescribing habits of the physicians who took them, including on information and belief, and based on the United States Attorney's Office for the District of Massachusetts' indictment of Kapoor, Rosenberg.

196. Insys also hired Rosenberg's son as a sales representative, upon information and belief, in an effort to reward and encourage his prescribing, although at one point in 2013 he was replaced in the Rhode Island territory by Natalie Levine, another detailer who covered much of the New England area and has since plead guilty to conspiring to provide kickbacks to prescribers. According to Levine's indictment, on at least one occasion, Insys paid Rosenberg for a talk at which no other prescribers were present and Rosenberg forged the signature of a prescriber he knew but did not attend to make the event appear legitimate. Records provided to Rhode Island by Insys show that Rosenberg received $3,200 six days later. The individual whose name Rosenberg forged on the sign-in sheets also appears on a list of attendees at seven separate events, including separate events on September 4, 11, and 12 of 2013, in addition to the event on October 3, which was the first attended by Levine.

197. Even after Rosenberg entered into a consent order with the Rhode Island Department of Health on September 8, 2014, recognizing that Rosenberg had prescribed Subsys off-label and reprimanding him for poor record keeping,[87] Insys continued to pay him for sham speaker programs. Rosenberg received two payments of $2,200 the very next day, and a total of

[86] Lisa Chedekel, High-Prescribing Nurse Charged with Accepting Drug Company Kickbacks, Connecticut Health I-Team, June 23, 2015. Katie Thomas, Nurse Pleads Guilty to Taking Kickbacks From Drug Maker, New York Times, June 25, 2015.
[87] http://health.ri.gov/discipline/MDJerroldRosenberg.pdf

$66,850 for 28 programs until his speaker programs finally ended in July 2015.

198. Insys' kickback scheme and misleading marketing of Subsys as appropriate for non-cancer pain contributed to the opioid epidemic in Rhode Island. One of Rosenberg's patients, dosed with more than 400 mg MED Subsys per day (more than 4 times the CDC recommended maximum daily dosage of all opioids), experienced significant side effects including weight loss and lethargy and wanted to quit the drug, but her doses were so high other prescribers were not willing to take her on as a patient, and so she continued to see him for pain treatment, and he continued prescribing Subsys to her. In one case, Rosenberg switched a patient from an opioid that the patient found more effective than Subsys and would not switch it back even when she told him she did not respond well to Subsys. Another Rosenberg patient on 576 mg MED of Subsys nearly died in Rosenberg's office during a visit; another patient on 432 mg MED of Subsys reported overdosing two different times.

199. Upon information and belief, these drugs continued to be approved by private insurers because of false statements made to them by the Insys Reimbursement Center, including misrepresentations regarding their pain conditions. Only one patient of those who testified at his sentencing had cancer, but his treatment was for pain from post-surgery scar tissue rather than breakthrough tumor pain. Others experienced headaches, back pain, or other chronic non-cancer conditions. Rosenberg even told one patient Subsys was specifically for chronic pain. Rosenberg was informed by a benefits manager that one of his patients was suspected of drug seeking behavior, yet nevertheless prescribed her high doses of Subsys. When an insurance company realized the patients did not have cancer and the drug was not appropriate, Rosenberg cut them off, subjecting them to painful and difficult withdrawal.

## VI. TEVA ILLEGALLY MISREPRESENTED THE RISKS AND BENEFITS OF ITS OPIOIDS

A. TEVA MISCHARACTERIZED THE RISKS OF OPIOIDS AS A CLASS

200. Teva has manufactured two main branded opioid products, Actiq and Fentora, as well as a number of generic opioids, and sold generic versions of OxyContin between 2005 and 2009. Actiq and Fentora are, like Subsys, TIRF opioids, which means they are extremely potent and more limited in indication than other opioids. Actiq was first approved in 1998, and indicated for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. References to cancer thus appeared three times in one sentence of the indication. Cephalon acquired the rights to Actiq in 2000, and by 2002, By 2002, Actiq sales had increased by 92%, which Cephalon attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[88] Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[89]

201. Evidence of off-label promotion of Actiq (as well as two other non-opioid drugs) led Cephalon to enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services, and to pay $425 million in civil and criminal penalties. According to a DOJ press release, Cephalon had trained sales representatives to disregard restrictions of the FDA-approved label, employed sales

[88] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), https://www.sec.gov/Archives/edgar/data/873364/000104746903011137/a2105971z10-k.htm.
[89] *Id.*

representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs and funded CME to promote off-label uses. When Teva acquired Cephalon in 2011, it stepped into Cephalon's shoes for purposes of the Corporate Integrity Agreement.

202. Teva's predecessor faced another problem with Actiq, however, which was impending generic competition. To stave off loss of marketshare. Cephalon introduced Fentora in 2006, which similar to Actiq, is a TIRF opioid approved only for the treatment of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Cephalon, and later Teva, thus began a program to migrate patients who were taking Actiq to Fentora, as well as to start new patients on Fentora.

203. However, On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied the application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

204. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Teva nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It

further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

205. Despite this warning, Teva continued to use the same sales tactics to push Fentora as it did with Actiq, including (a) promoting the use of opioids for the treatment of chronic non-cancer pain, Actiq or Fentora can only be prescribed to patients already taking opioids; and (b) to encourage the use of Fentora in non-cancer settings.

206. For example, Teva sponsored and facilitated the development of a guidebook, Opioid Medications and REMS: A Patient's Guide, which included claims that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." Similarly, Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

207. In 2003 a Teva-sponsored CME presentation titled Pharmacologic Management of Breakthrough or Incident Pain, posted on Medscape in February 2003, recites:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

208. Further, in 2007, Teva, along with Purdue, sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid

agreements between doctors and patients can "ensure that you take the opioid as prescribed."[90] This publication also taught patients that opioids have "no ceiling dose" and therefore are safer than NSAIDs. The publication also falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200. Teva also sponsored the Federation of State Medical Boards' ("FSMB") *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, which are signs of genuine addiction, are all really signs of "pseudoaddiction."

209. Teva's misrepresentations concerning opioids as a class benefitted its sales of both branded and generic opioids.

B. TEVA PROMOTED ITS FENTANYL OPIOIDS FOR OFF-LABEL USES

210. Teva 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 Teva 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.

211. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug

[90] By 2011, APF was dependent on Purdue, Teva, and others for funding. Despite its ties to and dependence on Defendants, APF held itself out as an independent organization. In 2012, the U.S. Senate Finance Committee began looking into APF's to ascertain any links between the organization and the manufacturers of prescription opioids. Within days of becoming a target of this investigation, the APF voted to dissolve. APF then closed its doors and declared that the organization had ceased to exist.

and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

212. As with Subsys, to reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS"), which was approved in 2011 and in effect in 2012. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them."[91] Prescribers must enroll in the TIRF REMS before writing a prescription for Actiq or Fentora.

213. Despite this, Teva 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, or safe. As part of this campaign, Teva 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 non-cancer pain.

214. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora, and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain." Indeed, FDA specifically denied Cephalon's application, in 2008, to broaden the indication of Fentora to include treatment of non-cancer breakthrough pain and use in patients who were not already opioid-tolerant.

215. Flagrantly disregarding the FDA's refusal to broaden the indication for Fentora, Teva nonetheless marketed Fentora beyond its approved indications. On March 26, 2009, the FDA warned Teva against its misleading advertising of Fentora ("Warning Letter"). The

[91] Press Release, FDA, FDA Approves Shared System REMS for TIRF Products, Dec. 29, 2011.

Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

216. Despite this warning, Cephalon continued to use the same sales tactics to push Fentora. For example, on January 13, 2012, Cephalon published an insert in Pharmacy Times titled "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert states: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."

217. Teva also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated $15 million in sales. By 2002, Actiq sales had increased by 92%, which Teva attributed to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists." Actiq became Cephalon's second best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."

218. Within Rhode Island, of the 13 prescribers for whom Teva provided payments from 2013-2016 relating to Fentora (including 4 visits to Jerrold Rosenberg), none were

oncologists.

219. Teva also spread misleading messages through its sponsorship of continuing medical education programs. Although ostensibly neutral, Teva used the same vendors and sponsors multiple times, and certain of the faculty had prior relationships with Teva, including acting as promotional speakers or consultants. These CME also encouraged off-label uses of Teva's TIRF opioids.

220. In 2007, Teva sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate," published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Lynn Webster, discussed below) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients." The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Dr. Portenoy and recommends fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.

221. Teva sponsored a CME written by pro-opioid physician Dr. Lynn Webster, who also acted as a consultant to Teva entitled, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as

aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

222. Another Teva-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who treated "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[92] The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

223. Teva 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 "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

224. In December 2011, Teva widely disseminated, including on information and belief, in Rhode Island, a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" Anesthesiology News, Clinical Oncology News, and

[92] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, http://www.medscape.org/viewarticle/461612 (last visited Oct. 10, 2017).

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.

225. The level of specificity included in the Teva-sponsored CME uniquely describe Teva's products render these CMEs impermissibly promotional, and the fact that speakers such as Webster acted as Teva consultants, and continued to do so after these off-label promotional materials appeared, suggests a concrete purpose to use CME channels to promote its products for off-label uses. By enlisting accrediting agencies in support of their branded promotional efforts, as well, Teva was able to change the medical consensus in favor of a dangerous off-label use of its fentanyl products, one specifically prohibited by the FDA.

### *V.* Allergan Misrepresented the Safety and Efficacy of Kadian

226. In December 2008, Allergan, through the Former Actavis Entities, acquired branded Kadian and began marketing around that time. Actavis promoted its branded Kadian through a highly deceptive marketing campaign that it carried out principally through its sales force. At the peak of Actavis's promotional efforts in 2011, the company spent $6.7 million on detailing. A year after Actavis began marketing branded Kadian, the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent Actavis a warning letter regarding Actavis' marketing. DDMAC warned that Actavis' marketing omitted and minimized Kadian's serious risks, misleadingly implied that Kadian was indicated for a broader range of conditions, and made misleading and unsubstantiated superiority claims. According to the DDMAC's warning, "[p]romotional materials are misleading if they represent or suggest that a drug is safer or more effective than another drug, when this has not been demonstrated by substantial evidence or substantial clinical experience." Actavis' marketing claimed Kadian had "[f]ewer peaks and valleys" and would "[a]llow for less breakthrough pain and more consistent

pain relief for patients" even though Actavis lacked the evidence and experience to support those claims.

227. Further, a 2010 Kadian sales training module represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction" and, instead, "[i]t appears likely that most substance-abusing patients in pain management practices had an abuse problem before entering the practice." This falsely suggests that few patients will become addicted, that only those with a prior history of abuse are at risk of opioid addiction, and that doctors can screen for those patients and safely prescribe to others. Upon information and belief, misrepresentations in Kadian sales trainings were conveyed to prescribers in Rhode Island.

228. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and cause patients to "enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." Upon information and belief, these statements were disseminated in Rhode Island.

229. Actavis also commissioned surveys of prescribers to ensure Kadian sales representatives were promoting the "steady-state" message. That same survey—paid for and reviewed by Actavis—found repeated instances of prescribers being told by sales representatives that Kadian had low potential of abuse or addiction. This survey also found that prescribers were

influenced by Actavis's messaging. A number of Kadian prescribers stated that they prescribed Kadian because it was "without the addictive potential" and wouldn't "be posing high risk for addiction." As a result, Actavis's marketing documents celebrated a "perception" among doctors that Kadian had "low abuse potential." This take-away is false and misleading as Kadian is a Schedule II opioid. Upon information and belief, Actavis engaged in false and misleading marketing that Kadian had low abuse potential to Rhode Island prescribers.

230. In addition to the misleading and unsubstantiated claims highlighted in DDMAC's warning letter, Actavis also grew Kadian sales by misrepresenting that Kadian patients could exhibit symptoms of pseudoaddiction for inadequately treated pain, that Kadian had a low abuse potential, that Kadian had no maximum or ceiling dose, and that Kadian had negligible risk of alcohol-induced dose-dumping.

## VII. Teva and Allergan's Misrepresentations and Aggressive Marketing Further Fueled the Expansion of the Generic Opioids Market

231. Defendants' deceptive marketing of opioids as a class benefited their generics business, as well as their branded products. For example, Teva and Allergan, through the Former Actavis Entities, had sophisticated and well-developed marketing departments, and they used the sales force to promote generic opioid products. Actavis's top opioid products included generic versions of Opana ER (oxmorphone ER), Kadian and MS Contin (morphine sulfate ER), and generic fentanyl. Teva sold a generic version of OxyContin (oxycodone ER) between 2004 and 2007, and again from 2016 to the present; as well as its own version of oxymorphone ER, a generic version of Actiq, and short-acting immediate release opioids. Teva also sells generic versions of addiction treatment drugs, including buprenorphine, and naloxone, an opioid overdose treatment drug.

232. Actavis used its branded sales force to promote generic opioids. Not long after

Actavis received DDMAC's warning letter regarding its branded Kadian misrepresentations, Actavis sought FDA approval for generic Kadian, which was granted in late 2011. The marketing launch for generic Kadian included direct mail and email campaigns as well as detailing through the Kadian sales team. One of the primary messages of the campaign was Kadian's long history of safe and effective use. The generic Kadian training for the sales team encouraged sales representatives to emphasize "[n]ow you can prescribe the same KADIAN with it's long history of safety and efficacy at a generic price." Actavis made these claims to prescribers even though it knew there was a "complete lack of clinical data for Kadian."

233. Further, despite DDMAC's warning, Actavis continued to use misleading and unsubstantiated superiority claims to market Kadian. A September 2012 sales training, for example, highlighted the message that Kadian patients "[e]xperience sustained morphine release with less fluctuations vs. morphine sulfate," "[r]eport improved management of pain vs. morphine sulfate," and "[r]equire less rescue medication vs. morphine sulfate."

234. The ultimate goal of Actavis' sales team was to drive the growth of Actavis' generic business by growing the overall market for Kadian. To facilitate this growth, the sales team was encouraged to sell "prescribers on the features and benefits of [Kadian] just like you've always done."

235. Further, in December 2010, Actavis received approval for generic Opana (Oxymorphone) and launched an aggressive marketing campaign in July 2011, focusing on the highest prescribing doctors. The marketing promotional plan noted that "[b]ecause Endo discontinued the 7.5 and 15mg strengths in March 2011, Actavis will be implementing a more aggressive promotional campaign for this launch." The launch plan included a two wave direct-mail campaign to the top 10,000 prescribers, using the Kadian sales team to deliver sellsheets to

pain doctors, and other marketing tactics. Actavis' goal was to "target physicians to continue to write and increase their scripts" of oxymorphone.

236. In March 2012, Actavis celebrated the success of its launch campaign. Actavis noted that the prescriptions increased to 50% of the amount prior to Endo's discontinuation of its branded Opana. Actavis attributed the increase in its generic prescriptions to "[c]ontinued promotion by Actavis (direct mail / email programs); and the help of the KADIAN sales team."

237. Teva also promoted its generic drugs by advertising price and availability to pharmacies and distributors, including promoting itself as having access to relevant manufacturing quota, after lobbying for expanded individual manufacturing quotas. In 2016, Actavis's generic business was sold to Teva while the branded business was retained by Allergan.

## VIII. MALLINCKRODT FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN RISKS OF OPIOIDS

238. Mallinckrodt contributed to Rhode Island's prescription drug crisis as a manufacturer of both branded and generic opioids. As a manufacturer of branded opioids, Mallinckrodt disseminated misleading messages about opioids for the treatment of chronic, non-cancer pain, including the benefits of ADF opioids, through both branded and unbranded channels. As a manufacturer of generic opioids, Mallinckrodt profited from its marketing and the sale of opioids for both legitimate prescriptions and diversion. Knowing this, Mallinckrodt failed to report suspicious orders, or even to have a system that would adequately identify them, thus contributing to the opioid crisis in Rhode Island.

### A. MALLINCKRODT FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION AND OVERSTATED OPIOIDS' EFFECT ON PATIENTS' FUNCTION AND QUALITY OF LIFE

239. Mallinckrodt promoted its branded opioids and opioids generally, in a campaign

that consistently mischaracterized the risk of addiction and made deceptive claims about functional improvement. Mallinckrodt conveyed these deceptive messages to Rhode Island prescribers through sales representatives, patient guides, and branded and unbranded websites and other marketing materials. It also disseminated deceptive messages through third party patient advocacy groups and professional associations who were financially tied to Mallinckrodt but seemed independent and, therefore, credible. Mallinckrodt distributed these messages, or facilitated their distribution, in Rhode Island with the intent that Rhode Island prescribers and/or consumers would rely on them in choosing to use opioids in general, and their opioids specifically, to treat chronic pain.

240. Mallinckrodt relies heavily on its sales representatives to convey its marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, Mallinckrodt's sales representatives visited prescribers in Rhode Island. Publicly available Open Payments Data[93] shows that between the third quarter of 2013 and 2016, Mallinckrodt sales representatives visited Rhode Island prescribers at least 157 times, in visits that included some sort of payment[94] to the doctor.[95] This number likely understates the amount of "detailing" by Mallinckrodt sales representatives, as it reflects only visits in which a payment was provided.

241. Mallinckrodt's promotional materials trivialized the risk of opioid addiction. Mallinckrodt's former parent Company, Covidien, published a "patient resource," called "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking

[93] Open Payments is a federal program that collects information regarding visits and payments to doctors from pharmaceutical and medical device companies. Pharmaceutical and medical device companies are required to disclose this information under the Physician Payments Sunshine Act in the 2010 Affordable Care Act.
[94] Payments include activities such as promotional speaking, consulting, travel, and meals.
[95] Centers for Medicare and Medicaid Services Open Payments Data, https://openpaymentsdata.cms.gov/.

opioid pain medicine as prescribed under the guidance of a healthcare provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."[96] The guide further explains that opioid tolerance is different from addiction, by explaining that tolerance may cause a patient to take more opioids in order to receive pain relief.

242. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that, "[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated" and cites to a report that concludes that "the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others."

243. Until at least June 2007, Mallinckrodt sponsored pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[97]

244. The FAQs section of pain-topics.org contained misleading information about a concept called "pseudoaddiction." Pseudoaddiction is a concept invented to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids, or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. Specifically, the pain-topics.org website described pseudoaddiction as behavior that occurs in

[96] CARES Alliance, "Opioid Safe Use and Handling Guide."
[97] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php, (Last visited May 7, 2018.)

patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications, and may be erroneously perceived as 'drug seeking."

245. The website also characterizes as "misinformation" the fact that patients who use opioids for long-term chronic pain become addicted, and questions why the daily administration of medications such as insulin and antidepressants is not considered addiction when the daily administration of opioids is. In addition, the website states that the constant media attention regarding opioid addiction, misuse and overdose creates a "false impression" that opioids should never be prescribed, and the number of "celebrities and street users" along with those who overdose from misuse is minimal in comparison to those who benefit from chronic opioid therapy.

246. Furthermore, pain-topics.org implies that if a patient is diagnosed with a pain condition and non-opioids fail to provide relief, that patient is "right" for opioids. The website also says that the practice of not using opioids for long-term pain is "nonsensical." It claims that patients who do not legitimately need opioids "do not exhibit obvious causes of pain" or provide other information such as MRIs, medical records, or an event which caused the chronic pain.

247. In addition, among its content, the website contained a handout titled Oxycodone Safety for Patients, which advised doctors that "[p]atients' fears of opioid addiction should be expelled." The handout stated the following misleading information regarding the risk of addiction: This handout is still available to prescribers and patients today.

248. Mallinckrodt also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs. Mallinckrodt's website, in a section on "responsible use" of opioids, claimed that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain

an active member of society."[98]

249. The Mallinckrodt-sponsored pain-topics.org website also claimed that long-term use of opioids for treatment of chronic pain conditions would improve patients' function. The website stated that the benefits of using opioids for chronic pain include improvement to functions such as eating, sleeping, socializing, sexual activity, driving, walking and working. The website also claims that chronic opioid administration improves "quality of life." The website further states that people who do not take opioids for long-term pain are "unable to participate in a normal family, vocational or other desired pursuits."

B. MALLINCKRODT MADE MISREPRESENTATIONS REGARDING ABUSE-DETERRENCE

250. Mallinckrodt oversold its "abuse-deterrent" opioids as a reason that doctors could continue to prescribe their opioids. Mallinckrodt's false and misleading marketing of the benefits of its abuse-deterrent opioids influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, "less safe" opioids—thereby prolonging the opioid epidemic.

251. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. However, neither drug has specific approval as a drug with abuse-deterrent properties. Nevertheless, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[99] To underscore the

[98] Mallinckrodt Pharmaceuticals, Responsible Use, http://www.mallinckrodt.com/corporate-responsibility/responsible-use.

[99] Mallinckrodt Press Release, FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-

limitations of the drug, however, one member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[100]

252. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."[101] In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[102] Upon information and belief, based on statements to prescribers in other jurisdictions and Mallinckrodt's centralized, national marketing, statements touting Xartemis XR's effectiveness in preventing abuse were made in Rhode Island.

253. None of Mallinckrodt's "technology" addresses oral ingestion, and its statements regarding abuse-deterrent formulations give the misleading impression that doctors need not worry about the abuse of these opioids. The above representations and resulting implications that Exalgo and Xartemis XR would prevent abuse and were, therefore, safer than other opioids were false and misleading.

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Severe Chronic Pain (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159

[100] http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf at 157-58

[101] Mallinckrodt, Responsible Use of Opioid Pain Medications (Mar. 7, 2014) at 14.

[102] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Business Journal (Dec. 30, 2013), available at http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/

## C. MALLINCKRODT DIRECTED FRONT GROUPS TO PROMOTE OPIOID USE AND COMBAT EFFORTS TO RESTRICT OPIOID PRESCRIBING

254. Patient advocacy groups and professional associations have been vehicles for Mallinckrodt to reach prescribers, patients, and policymakers. Mallinckrodt exerted influence and effective control over the messaging by these groups by providing funding directly to them. Mallinckrodt funded front groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

255. "Patient advocacy organizations and professional societies … play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."[103] "Even small organizations—with 'their large numbers and credibility with policymakers and the public'—have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[104]

256. Upon information and belief, by funding front groups, Mallinckrodt was able to exercise control over their false and deceptive messages. Mallinckrodt acted through the front groups to deceptively promote the use of opioids for the treatment of chronic pain, and to press for policies and legislation that would advance its interests.

257. Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization that styles itself as a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical

[103] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, February 12, 2018 https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 2.
[104] *Id*.

care.As of January 2018, the APA listed 30 "Associate Members and Financial Supporters," which includes Mallinckrodt.[105] It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006.[106]

258. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[107] Among other things, the white paper criticizes prescription monitoring programs,[108] purporting to express concern that they are burdensome, not user friendly, and of questionable efficacy:

> Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.
>
> * * *
>
> In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription

[105] APA's board members, including Dr. Robert A. Yapundich, Dr. Jack D. Schim, and Dr. Howard Hoffberg, have also directly received funding from pharmaceutical companies including Mallinckrodt. See ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/

[106] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/

[107] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

[108] Prescription monitoring programs, such as Rhode Island's Prescription Drug Monitoring Program serve to curb diversion by providing physicians with access to information regarding prescriptions of controlled substances patients have received during a certain period of time.

> monitoring programs represents a system based on punishment as opposed to incentives. . . .
>
> We cannot merely assume that these programs will reduce prescription pain medication use and abuse.[109]

259. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . . [I]t is not even certain that the regulations are helping prevent abuses.[110]

260. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal. . . . Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.[111]

261. In conclusion, the white paper advocates for the use of opioids for chronic pain, stating, "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or

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[109] Prescription Pain Medication: Preserving Patient Access While Curbing Abuse, Institute for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s. wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.
[110] *Id.* at 5-6.
[111] *Id.* at 6.

experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[112]

262. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the "suspicious orders" provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* ("CSA" or "Controlled Substances Act").[113] An internal U.S. Department of Justice ("DOJ") memo stated that the proposed bill "'could actually result in increased diversion, abuse, and public health and safety consequences'"[114] and, according to DEA Chief Administrative Law Judge John J. Mulrooney, the law would make it "all but logically impossible" to prosecute manufacturers and distributors, like Mallinckrodt here, in federal courts.[115] The law passed both houses of Congress and was signed into law in 2016. These efforts to prevent the implementation of programs and statutes that are designed to prevent diversion are in direct contravention of Mallinckrodt's public claims that it is committed to fighting opioid misuse and preventing diversion. *See* ¶¶ 355, *infra.*

263. The U.S. Pain Foundation ("USPF") was another front group with systematic connections and interpersonal relationship with Mallinckrodt. The USPF was one of the largest

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[112] *Id.* at 7.
[113] Letter from Alliance for Patient Access, et al., to Congressmen Tom Marino, Marsha Blackburn, Peter Welch, and Judy Chu (Jan. 26, 2015). http://www.hoparx.org/images/hopa/advocacy/advocacy-activities/FINAL_Patient_ Access_Letter_of_Support_House_Bill.pdf.
[114] Bill Whitaker, Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 2017), https://www.cbsnews.com/news/ ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (hereinafter, "Whitaker, Opioid Crisis Fueled by Drug Industry").
[115] John J. Mulrooney, II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marquette L. Rev. (forthcoming Feb. 2018), https://www.documentcloud.org/ documents/4108121-Marquette-Law-Review-Mulrooney-Legel.html.

recipients of contributions from the Mallinckrodt and other opioid makers, collecting nearly $3 million from opioid makers in payments between 2012 and 2015 alone. The USPF was also a critical component of Mallinckrodt's lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to Mallinckrodt, listing opioid manufacturers like Mallinckrodt, as "Platinum," "Gold," and "Basic" corporate members.[116] Industry front groups like the American Academy of Pain Management, the American Academy of Pain Medicine, the American Pain Society, and PhRMA are also members of varying levels in the USPF.

264. The USPF has made several misleading statements regarding opioids. For example, USPF claims that opioid treatment allows patients to function.[117] Additionally, Paul Gileno, the founder and president of the USPF, claimed that opioids allow people to "participate in daily life and be contributing members of society."[118] The USPF made further misleading statements, including statements that involve veterans. For example, the USPF website discusses recent opioid prescribing guidelines released by the Department of Veteran Affairs and Department of Defense. The USPF describe these guidelines as "problematic" due to their advice to prescribe 20-50 morphine milligram equivalents ("MME") per day with caution, and their warning against prescribing more than 90 MEEs per day. The group also suggests untreated chronic pain creates a risk of suicide, and therefore physicians should not necessarily be cautious in prescribing opioids to those with suicidal ideation.[119]

265. Upon information and belief, Mallinckrodt would not have supported these

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[116] *Id*. at 12; Transparency, U.S. Pain Foundation, https://uspainfoundation.org/transparency/ (last accessed on March 9, 2018).
[117] U.S. Pain Foundation, New Coalition Calls for Balanced Approach to Opioids, available at https://uspainfoundation.org/news/new-coalition-calls-balanced-aproach-opioids/.
[118] Id.
[119] U.S. Pain Foundation, VA Restricts Opioids for Veterans and Military Service Members, available at https://uspainfoundation.org/news/va-restricts-opioids-veteran/.

organizations if they did not disseminate messages that promoted Mallinckrodt's business objectives in promoting the use of opioids for chronic, non-cancer pain, leaving Mallinckrodt with effective control over their messages and undermining their appearance of independence.

### D. MALLINCKRODT TOLD DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS

266. Through third parties, Mallinckrodt falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Mallinckrodt apparently needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary.

267. Through its funding of the website pain-topics.org, Mallinckrodt claimed that there is no ceiling dosage for opioids, and that dosage should be determined by starting on low dosages and titrating up until a patient finds relief. The website does not disclose the dangers associated with higher doses, but claims that risks associated with opioids, such as death, overdoses and accidents, occur when patients do not take opioids as prescribed, or when the patient is taking other drugs or substances unknown to the prescribing doctor.

268. These claims conflict with the scientific evidence, including the known risks of high doses discussed above.

## IX. PURDUE, MALLINCKRODT, ALLERGAN, TEVA, AND THE DISTRIBUTOR DEFENDANTS DELIBARTELY DISREGARDED THEIR DUTIES TO REPORT AND TERMINATE SUSPCIOUS ORDERS

A. MANUFACTURERS AND DISTRIBUTORS HAVE A DUTY TO REPORT SUSPICIOUS ORDERS AND NOT SHIP THOSE ORDERS UNLESS DUE DILIGENCE DISPROVES THEIR SUSPICIONS

269. The Defendant Distributors compounded the harm of deceptive marketing of opioids, described above, by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of Purdue, Mallinckrodt, Teva, Allergan, and Distributor Defendants to investigate, report, and terminate orders that they knew or should have known were suspicious, such as orders affiliated with the pill mills described above, breached both their regulatory and common law duties to Rhode Island.

270. First, by flooding Rhode Island with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that it should have realized were likely being diverted for illicit uses, Distributor Defendants. Purdue, Teva, Allergan and Mallinckrodt breached their duty to exercise reasonable care in delivering narcotic substances and both created and failed to prevent a foreseeable risk of harm to Rhode Island.

271. Under the Rhode Island Controlled Substances Act, R.I. Gen. Laws §§ 21-28-3.01, *et seq.*, each manufacturer, distributor, prescriber, or dispenser of any controlled substances must maintain "effective controls against diversion," and "comply with applicable federal, state, and local law," or else risk loss of license and other action. R.I. Gen. Laws §§ 21-28-3.03, 3.04, and 21-28-3.28. Thus, Rhode Island law imposes its own duty on participants in the chain of supply of controlled substances to prevent their diversion.

272. Under the Federal Controlled Substances Act, Manufacturing and Distributor Defendants are required to register annually with the U.S. Attorney General in accordance with federal rules and regulations. *See* 21 U.S.C. § 822(a)(1). Any registration must be consistent with the public interest based on a consideration of, among other factors: 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. *See*, 21 U.S.C. § 823.

273. Federal regulations further mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the [U.S. Drug Enforcement] Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."[120]

274. In sum, Distributor Defendants, along with Defendants Purdue, Teva, Allergan, and Mallinckrodt, have several responsibilities with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. Second, they 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, they can determine that the order is not likely to be diverted

[120] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. (the DEA), U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006)(hereafter Rannazzisi Letter, Sept. 27, 2006).

into illegal channels.[121] And, third, all flagged orders must be reported to relevant enforcement authorities.[122]

*I. Defendants Understood the Importance of Their Reporting Obligations*

275. The purpose of the reporting rules is to create a "closed" system intended to reduce the 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.[123]

276. Trade organizations to which the Distributor Defendants belong have acknowledged that wholesale distributors such as the Distributor Defendants have been responsible for reporting suspicious orders for more than 40 years.[124] The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[125] Guidelines established by the

[121] *See Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017) (Describing the "Shipping Requirement" as requiring the distributor to decline to ship the suspicious order, or to ship the order only if due diligence demonstrates that the order is not likely to be diverted into illegal channels).
[122] *Id*.
[123] *See* 1970 U.S.C.C.A.N. 4566, 4571-72.
[124] *See* Brief for HDMA and NACDS, *supra* note 85, 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).").
[125] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as *Amici Curiae* in Support of

HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customer."[126]

277. The DEA also repeatedly has made clear that Defendant Distributors' and Manufacturers' obligations obligate them to report and decline to fill suspicious orders. The DEA, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included the Distributor Defendants) that they 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."[127] The DEA's September 27, 2006 letter also expressly reminded the Distributor Defendants that registrants, *in addition* to reporting suspicious orders, have 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."[128]

278. The DEA sent another letter to each of the Distributor Defendants, and to the

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Neither Party, *Masters Pharmaceuticals, Inc. v. DEA*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[126] 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 at 1).

[127] *See* Rannazzisi Letter, Sept. 27, 2006, ("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 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

[128] *See* Rannazzisi Letter, Sept. 27, 2006.

Purdue as well, on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, 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."[129] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the 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."[130]

### *II. Purdue, Teva, Allergan, Mallinckrodt, And Distributor Defendants Have Repeatedly Violated Their Reporting Requirements*

279. Defendant Distributors, have faced repeated faced enforcement actions for their failure to comply with their obligations to report and decline suspicious, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them:

a. 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 a 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;

b. 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

[129] *See* Letter, Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, DEA, 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.
[130] *See* Rannazzisi Letter, Sept. 27, 2006.

Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. 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;

d. 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;

e. 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;

f. 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";

g. 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"); and

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Lakeland Facility for failure to maintain effective controls against diversion of oxycodone. This *Order* alleged, among other things, that Cardinal Lakeland failed to conduct "meaningful due diligence of its retail pharmacy customers, including its retail chain pharmacy customers, to ensure that controlled substances were

not diverted into other than legitimate channels."[131] The *Order* resulted in a two-year suspension of Cardinal's registration to distribute Schedule II narcotics from the Lakeland Facility.

280. These violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders that would have affected Defendant Distributors' operations in and the supply of opioids into Rhode Island.

281. Defendant McKesson recently admitted to breach of its duties to monitor, report, and prevent suspicious orders and agreed to pay a $150 million civil penalty for the violations. 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."[132] 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)."[133] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular

[131] *Settlement Agreement* at para. G (1), December 20, 2016
[132] 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."), available at https://www.justice.gov/opa/press-release/file/928471/download.
[133] Id.

controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300, *et seq*., at the McKesson Distribution Centers." These violations, upon information and belief, took place at the distribution centers supplying the Rhode Island area and permitted diversion of prescription opioids into Rhode Island.

282. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as $1 billion, and delicensing of certain facilities.[134] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[135]

283. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[136] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[137] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[138]

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[134] Lenny Bernstein and Scott Higham, "'We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper, Washington Post (Dec. 17, 2017).
[135] *Id.*
[136] *Id.* (alteration in original).
[137] *Id.* (quoting a March 30, 2015 DEA memo).
[138] Id.

"Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[139]

284. Purdue's failure to report suspicious activity was the subject of detailed reporting by the *Los Angeles Times*, which relied, in part, on internal Purdue documents and interviews with former employees and law enforcement. Since at least 2002, Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids. Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion).[140] Health care providers added to the database were supposedly no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

285. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. In an interview with the *Los Angeles Times*, which first reported this story, Purdue's former senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

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[139] *Id*.

[140] Harriet Ryan, Lisa Girion, and Scott Glover, "More Than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew," *Los Angeles Times,* July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/

286. The same was true of prescribers. For example, despite Purdue's knowledge of illicit prescribing from one Los Angeles, CA clinic which its district manager called an "organized drug ring," Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

287. The New York Attorney General found that Purdue placed 103 New York health care providers on its No-Call List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite extensively, making more than a total of 1,800 sales calls to their offices over a six-year period" and spending approximately $3,000 dollars in meal expenses for 38 of these providers.[141]

288. In Rhode Island, for example, Purdue detailed another prescriber for three years after he told Purdue in a sales call that he was on the "DEA's radar" for prescribing to patients who were diverting their products (calling in early refills despite not actually taking the drug per the patients' toxicology screenings). Purdue also detailed Jerrold Rosenberg even after a *New York Times* article discussing his relationships with Insys appeared and despite previous reporting to the Abuse and Diversion Detection program. Purdue also detailed a prescriber, Dr. Bartel Crisafi, five months after he told the Purdue sales representative he was disciplined for overprescribing, and continued to detail Dr. Crisafi through at least June 2017. Purdue not only continued to market its drugs to these prescribers, but failed to report any of them to the Rhode Island Board of Medical Licensure & Discipline.

289. Dr. Crisafi wrote 40 prescriptions of Purdue opioids covered by Rhode Island's

[141] Attorney General of the State of New York, In the Matter of Purdue Pharma L.P., Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

Medical Assistance program resulting in charges of $41,619.29. Dr. Rosenberg wrote 189 prescriptions of Purdue opioids covered by Rhode Island's Medical Assistance program resulting in charges of $29,980. These are provided as examples of improper claims paid for by the State of Rhode Island, but represent only a fraction of claims that resulted from Purdue's failure to report suspicious prescribing and its fraudulent marketing.

290. When Purdue learned one prescriber, Dr. Fathalla Mashali, was under investigation in Rhode Island, it barred its sales representatives from seeing him in this state but continued to visit him at separate clinics he operated in Massachusetts. Purdue had a system of red flags for suspicion prescribing and diversion. On information and belief Purdue observed red flags at clinics he operated, including overbooking patients, visiting patients outside of examination rooms, high rates of staff turnover, and destruction of medical records.

291. Dr. Fashali ultimately lost his license to practice medicine in Rhode Island in August 2013, following an investigation that found, *inter alia*, that he continued to prescribe opioids to patients he knew to be using them improperly, including at least one who died of an overdose. The Rhode Island Department of Health found Dr. Mashali to be an "immediate threat to the health, welfare and safety of the public" in revoking his license. During the time the Rhode Island case was pending, however, he continued to see patients, including, upon information and belief, Rhode Island residents, in Massachusetts and other patients who diverted drugs to Rhode Island. Purdue sales representatives did not stop detailing him or, upon information and belief, report him to law enforcement or disciplinary authorities. Ultimately Dr. Mashali pleaded guilty to defrauding Medicare in Massachusetts in 2017 and was sent to prison for 8 years.

292. Purdue has long been aware that its drugs, in particular OxyContin, have been

diverted from legitimate channels, including both that certain prescribers write prescriptions knowing they are not for any legitimate medical purposes, and that throughout the supply chain, its pills are targets for theft. This concern was part and parcel of Purdue's efforts to obtain exclusivity for a tamper resistant OxyContin, discussed above. Purdue did not, however, take necessary steps to ensure that it did not fuel a black market in its opioids.

293. Purdue had knowledge of criminal diversion in the late 1990s and early 2000s, both nationally and in Rhode Island. CVS pharmacy notified Purdue in 2002 that in the Boston region (encompassing Rhode Island), it considered no longer stocking OxyContin given that CVS stores alone experienced more than 100 robberies per year. CVS conveyed that not only were the robberies damaging to society as a whole, but that rendered OxyContin unprofitable to stock, led staff to quit, and forced CVS to invest in upgrading security systems at its own cost.. Although in 2002, Purdue agreed to finance the cost of some of these security upgrades Purdue did not address the root of the problem – the oversupply of its opioids and the demand for their non-medical use. A 2002 memo noted "[s]everal accounts [i.e., customers] have said that OxyContin, not prescription drug abuse, is the issue." Purdue sought to respond to the immediate financial needs of pharmacies when its own needs were threatened, but did not take steps such as reducing the supply of opioids and truthfully marketing their risks.

294. In addition, as laid out in greater detail below, Mallinckrodt deceptively and unfairly failed to put into place appropriate procedures to ensure suspicious orders would be reported to authorities and instead, continued to fill orders which supplied far more opioids than were justified. This is notable in Rhode Island's case as Mallinckrodt was the largest supplier of opioids by dosage unit to Rhode Island customers from 2006-2014. Each of Mallinckrodt's shipments of opioids into the stream of commerce in Rhode Island without an adequate system in

place to investigate, report, and refuse to fill orders that they knew or should have known were suspicious violated both its common law duties and its statutory duties under Rhode Island law.

295. In 2011, the DEA began to investigate Mallinckrodt after DEA investigators noted large amounts of Mallinckrodt's oxycodone being sent to Florida.[142] In 2017, Mallinckrodt paid a $35 million fine for its failure to put into place appropriate procedures to ensure suspicious orders would be reported, and its failure to report suspicious orders.[143] It further entered in to a Memorandum of Agreement in 2017 (the "MOA") which obligated Mallinckrodt to use "all available transaction information" to identify and report suspicious orders. The deficiencies uncovered by the DEA were at a company-wide level, not limited to shipments to Florida. In addition, as a result of their failings in Florida, drugs distributed to that state supplied a national black market including, upon information and belief, in Rhode Island.

296. The Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 to 2012, which was 66% of all oxycodone sold in the state. According to the *Washington Post*, an internal summary of the federal case against Mallinckrodt found that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"

297. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt "did not meet its obligations to detect and notify DEA of suspicious orders of

[142] Lenny Bernstein and Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable,* The Washington Post, April 2, 2017.
[143] 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.

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 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' . . ."[144]

298. 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."[145]

299. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> a. 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;
>
> ii. detect and report to the DEA orders of unusual size and frequency;

[144] *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.
[145] *Id.*

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.[146]

300. In connection with the settlement, Mallinckrodt admitted that "[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."[147] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would

[146] 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"), at 2-3.
[147] *Id.* at 1.

"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."[148] Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[149]

301. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, certain aspects of 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."[150]

302. Mallinckrodt's actions as laid out in the MOA allowed opioids to enter illicit channels of commerce, including upon information and belief in Rhode Island. However, both before and after the MOA was put into place, Mallinckrodt did not report any suspicious orders in Rhode Island.

303. Teva, for its part, as the second largest supplier of opioids by dosage units to Rhode Island from 2006-2014 was in a position to identify suspicious orders; but it did not make any reports to the Rhode Island Department of Health or, on information and belief, to any federal entity with jurisdiction in Rhode Island, concerning any Rhode Island pharmacy's orders.

304. Teva Allergan Entities also had detailed information about pharmacies and stocking of its products, relying on Defendant McKesson to identify the high purchasing pharmacies to target them for generic marketing. Additionally, a former Allergan Director of Product Marketing for generic prescriptions testified in the MDL that McKesson was paid to call

[148] Id. at 4.
[149] Id.
[150] Id.

pharmacies to help with stocking of a new oxymorphone offering Allergan was launching. McKesson was to be rewarded for this work upon Allergan being provided "proof of store stocking in a period of 30 days." [151]

305. Further, Defendants also assumed the duty in their internal documents and when speaking publicly about opioids and their efforts and commitment to prevent diversion of prescription opioids. Defendants made statements to the media, regulators, and the public at large claiming to take all reasonable precautions to prevent drug diversion. For example, Allergan publicly touted its purportedly state-of-the-art SOM systems and processes, and professed its commitment to legal compliance and combatting diversion as evidence of its corporate responsibility.[152]

B. Allergan's Failures to Prevent Diversion

306. Allergan's SOM system included separate systems operated by Watson Pharmaceuticals, Inc. ("Watson") and Actavis, Inc., which Watson bought in 2012-2013, and by Allergan, which the merged companies then bought in 2015. Neither of the two prior companies, nor the merged group, maintained effective controls against diversion.

307. Before the year-end 2012 merger, Actavis, Inc. produced twelve different generic opioids, including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and a generic version of Janssen's Duragesic. Meanwhile, from November 2000 through October 2012, the

[151] Jinping McCormick Tr. at 141:3-4, 142:6-24 & 155:22-156:15.
[152] https://www.allergan.com/investors/%E2%80%9D/-/media/allergan/documents/us/Investors/Annual-Reports/2012-10-K-Annual-Reports.pdf%E2%80%9D; https://www.allergan.com/-/media/allergan/documents/us/Investors/Report-to-the-Stockholders-of-Allergan-Form-the-Board-of-Directors-Board-Report.pdf

company maintained the same rudimentary threshold-based SOM system. Under that system, a Customer Service group printed a report "several times a day" showing any controlled substance order that was "25% over the customer's rolling average" of orders placed over the prior six months. Then, "Customer Service [would] review[] (eyeball[]) the suspicious order report throughout the day (when a new report is created)" and "any order that look[ed] unusual [was] investigated and any unusual items [we]re cleared before the order [wa]s released."

308. This 2000-2012 system only flagged orders unusual in size; it did not flag orders unusual in frequency or pattern in real time, as the law required. It did not utilize any downstream customer information available to Actavis, Inc., did not differentiate among National Drug Codes ("NDC"s) for drugs with a higher risk of diversion, nor did it automatically stop orders from shipping. And, although Actavis, Inc. mailed reports to the DEA of orders that were identified in the system from 2009-2012, the lack of any analysis of such data, and the fact that Actavis, Inc. shipped the orders notwithstanding its suspicion, made the reports meaningless.

309. Further, although Actavis, Inc.'s marketing group designed a separate program starting in January 2011, that program tracked only "oxycodone IR suspicious orders." The marketing program compared monthly order rates and noted "any individual customer locations that have ordered 50% or greater than their established six month order average." However, it was not designed to track DEA regulations and appears to have been abandoned after only three months of trials.

310. Internal documents reflect that in September 2012, Actavis, Inc. was implementing a statistics-based, more modern SOM system designed by outside consultants from the Buzzeo/Cegedim group to detect "orders of interest" in "[d]irect Customer sales." On October 1, 2012, that system began working alongside Actavis, Inc.'s prior system.

311. Watson's pre-merger SOM system, like the early pre-merger Actavis, Inc. system, dated to the early 2000's. This system, however, was even more rudimentary. According to a 2001 memo, Watson's inventory system automatically compiled a "12-month average" of customers' various orders, and reported potentially suspicious orders to Customer Service personnel (also known as the "Call Center" group). A May 2004 Operational Procedure added a "SOMS multiplier table" to the system, which increased the level at which the inventory system would alert a potentially suspicious order. The multiplier placed a different value for various "classes of trade." Orders from wholesalers, distributors and chain pharmacies were regularly allowed at triple the historical average, or more.

312. The program was also understaffed. Between 2009 and 2012, the Watson Call Center/Customer Relations Operation added no new staff to handle the SOMs "validations," even though the number of validations increased substantially. Between 2009 and 2010 alone, the number of "SOMs validations" handled by each "administrator" jumped from 62 "SOMs validations" per month to an average of 180. In 2011, the number reached 280.

313. The Watson system was flawed, as well, in that it affirmatively allowed customers to get around violations by canceling the order or cutting its quantity. Shipping less of an order does not make it less suspicious; it means only that fewer suspicious drugs are shipped. Through 2012, Watson's consistent policy was not to report the order to DEA, but to simply cut or cancel the order instead. Beginning in 2012, Watson added to its requirements, but merely that "[i]f the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation." Before the merger with Watson, Actavis, Inc.'s internal documents reflect an understanding that "cutting" an order to a volume that places it beneath the threshold is unacceptable. According to its then-CEO, however, Actavis, Inc. allowed customers to resubmit

unjustifiable suspicious orders in smaller amounts so as to fall below their arithmetic suspicious order monitoring threshold, thereby avoiding reporting.

314. After the merger, the combined company reverted to the existing Watson SOM system, and cutting or cancelling suspicious orders without reporting them was not generally prohibited. Watson also allowed orders to be shipped based on an e-mail justification from an employee (including salespeople with a financial incentive to complete the sale).

315. As described above, like the pre-merger Actavis, Inc. system, the automated portion of Watson's system only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system did not utilize any downstream customer information and did not differentiate among NDCs for drugs with a higher risk of diversion. The SOM program was not an effective control against diversion.

316. On September 28, 2011, Watson received an audit report from the outside consulting firm, Buzzeo/Cegedim, regarding its SOM program. The problems were evident from the very first page: "Watson's current approach is based upon thresholds that are somewhat arbitrary and not in conformance to the specific requirements of the regulations." In its findings, Buzzeo/Cegedim noted that Watson's SOM program was based on the "class of trade" grouping and the application of a "multiplier," as discussed above. The report found that an individual order that was deemed in excess of the multiplier by the class of trade would then be "pended" for investigation by Watson staff, and that approximately 10% of "pended" orders were considered "orders of interest" and sent to security/regulatory for further review. Buzzeo/Cegedim found that, nationwide, Watson reported only one order to the DEA. In its recommendations, Buzzeo/Cegedim stated that due to the SOM system's inconsistences with the

"specific requirements noted in the regulations and with written guidance provided by the DEA to all registrants," Watson should "revisit its entire approach to SOM to fully address the specific regulatory requirements and other guidance documents provided by the DEA, to include evaluating all orders on the basis of size, frequency, and order pattern deviation.

317. The audit also found that certain accounts, such as McKesson and AmerisourceBergen, had "managed inventories" which are pre-set inventory levels. Watson staff could approve orders by these accounts when inventory was low. Buzzeo/Cegedim described this system as "self-gaming," and pointed out that reduced inventory is an indicator of increased product movement," and "not a justification for increased order size." Buzzeo/Cegedim recommended that Watson reform its SOM program to identify "unexplained changes in order behavior."

318. Finally, Buzzeo/Cegedim discussed Watson's report identified as "EDI 867" which showed who their customers were selling to. Buzzeo/Cegedim recommended that this report be incorporated into the SOM program.

319. Yet, Watson did not implement the changes Buzzeo/Cegedim recommended to bring its SOM system into compliance with DEA regulations. Its flawed system remained in place and was carried forward into the merged company.

320. In 2015, the merged company, now known as Allergan, announced it was selling all of its generic drugs and various corporate subsidiaries to Teva. It ceased operating even the deficient Watson SOMS program at that time. Now, Allergan outsources its manufacturing, transport and delivery systems, and is no longer a DEA registrant with regard to its branded opioids, Kadian and Norco. It appears Allergan takes the view that it is a "virtual manufacturer" and need not have a suspicious order monitoring system at all. DEA regulations recognize no

category of "virtual" manufacturers, and Allergan cannot delegate its duties to prevent diversion.

321. Even before 2015, internal documents show that both Watson and Actavis, Inc. employees recognized that the suspicious order monitoring systems described above were not an effective control against diversion.

322. In February 2009, the Senior Manager of Actavis Inc.'s Customer Service Department, Nancy Baran told her boss that the existing Actavis Inc. process was inadequate to "prevent shipping excess product" because it was not cumulative and because there were too many orders over the 25% threshold. Baran would later testify in *In Re: National Opiate Litigation*, MDL No. 17-02804 (N.D. Ohio) ("MDL") that she remembered only one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA. All other orders flagged by the system were shipped.

323. In a 2011 Project status review, Baran would also make clear that "'Cutting' orders to a volume that puts the order under a threshold is not acceptable." The same presentation explains that the "DEA has stated on this topic, 'That is like saying a little bit of diversion is okay'").

324. On September 12, 2012, at the same time Actavis, Inc. was preparing to implement the recommended Buzzeo/Cegedim SOM system, Actavis, Inc. had an approximately three-hour meeting with DEA personnel at the DEA's Arlington, Virginia office to discuss opioid diversion. At the meeting Barbara J. Boockholdt, Chief of the DEA's Regulatory Section, told Actavis, Inc.that its products were being distributed in Florida in quantities and under circumstances highly suggestive of diversion. Leonard Levin, Staff Coordinator of the DEA Regulatory Section told Baran that it should have a member of its compliance team visit certain pharmacies in south Florida, "get to know their customers, visit distribution sites, visit customers

of those distributors, check on customers' suspicious order monitoring systems, review due diligence files, and obtain printouts of pharmacies or practitioners who are receiving Actavis products," among other steps. Upon information and belief based on industry practices, however, Actavis, Inc. already had detailed information about its customers, prescribing doctors, and pharmacies. It simply used this information to advance their sales, rather than prevent diversion.

325. Actavis Inc.'s Ethics & Compliance Officer, Michael R. Clarke, testified in the MDL that "the tone and the tenor of the meeting" was such that it seemed the DEA was viewing and speaking with the Actavis Inc. representatives "as street dealers" rather than "as professionals." "[T]hey described it," Clarke said, "without using these specific words, but in a way that we would just manufacture, put the product out on the street, and not have a care as to where it went" and "described finding or seeing or obtaining product, you know, opioid products that seemed to be diverted relatively easily."

326. In late October 2012, Actavis, Inc. had a follow-up meeting with two field representatives from the DEA's Newark, New Jersey office where, according to Clarke, DEA requested a reduction of approximately 30%-40% in Actavis Inc.'s manufacturing quota for oxycodone. According to Clarke, Actavis's then CEO, Doug Boothe, rejected the DEA's request.

327. Further, like Nancy Baran at Actavis, Inc., Thomas Napoli at Watson made clear – internally— that the system did not comply with the DEA laws and regulations. In November 2008 Napoli wrote a memo stating that:

> It is highly recommended that industry utilize a 'total SOM model.' This model favors a more statistically-based model that dynamically evaluates a variety of order characteristics to determine whether an order should be pending. Characteristics include order size, ordering frequency, ordering patterns and

percentage of CS ordered.

His memo continued "[t]his approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold." A 2012 PowerPoint from Napoli's files also describes the feedback from Buzzeo/ Cegedim as critical.

328. Other internal Allergan emails show that, according to the employees responsible, the suspicious order monitoring system "d[id] a lousy job." One goes to explain that, "for example," "if a customer's monthly usage is 3000 units – they can order 2999 units every day of the month and it would not be caught." The same internal e-mail, from February 2009, states that orders in excess of the threshold "come in all day long" and "[i]t would be crippling". . . "[i]f Allergan stopped to question and put on hold every one of these orders." In another internal document, Allergan similarly acknowledged its program as "not consistent with specific requirements within the regulations and guidance."

329. As explained above, Allergan was, and should have been, well aware of its obligations. This is particularly true given that its branded opioid Norco was so widely diverted that it had the street name "Watson" – the name of the Allergan predecessor that brought the drug to market – and that the DEA blamed it for a "diversion wave." Further, the association between Allergan's predecessors and diversion was not limited to Watson. Actavis, too, was "frequently associated in social media, online message boards, and markets with inappropriate use and questionable distribution" of oxycodone; and its name was adopted by "performers such as 'DJ Actavis,' and songs such as 'Cream Soda and Actavis's."

330. Tellingly, however, former CEO Boothe testified in the MDL that he believed Actavis Inc.'s responsibility was only to making certain that orders were received from licensed pharmacies and were within numerical thresholds, and that Actavis Inc. had no responsibility (or

accountability) for preventing diversion:

> Again, I don't think we had responsibility for, accountability for preventing diversion. We had responsibility and accountability for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds as it was described earlier then with the Buzzeo model or the more statistical model. So we -- that was our responsibility. Once it goes outside of our chain of custody, we have no capability or responsibility or accountability to -- or at least my understanding, I'm not a lawyer, as it relates to diversion. So, once we ship a valid order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.

331. Allergan's failure to monitor suspicious orders and maintain effective controls to prevent diversion contributed to the spread of illicit opioids in Rhode Island, causing Rhode Island to incur costs to address opioid diversion, misuse, addiction, and overdose, among other consequences.

### C. SINCE 2014, AND UPON INFORMATION AND BELIEF, BEFORE THAT TIME, NO DEFENDANT REPORTED ANY SUSPICIOUS PRESCRIBER OR PHARMACY TO THE RHODE ISLAND BOARD OF PHARMACY.PURDUE AND THE DISTRIBUTOR DEFENDANTS WORKED TOGETHER TO SUSTAIN THEIR MARKETS AND BOOST SALES OF THEIR PRODUCTS

332. HDA's website indicates that each of the Distributor Defendants and Purdue were members of the HDA. Upon information and belief, the HDA and the Distributor Defendants sought the active membership and participation of Purdue and others by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels. The HDA touted the benefits of membership to the Purdue, 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."[153]

333. Through these organizations, Defendants lobbied for higher quotas and to weaken DEA enforcement. For example, acting through the HDA, Defendants lobbied for and drafted portions of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016, which raised the standard for the DEA to suspend a registrant. The HDA website confirms that Teva and Allergan are members of the HDA.[154]

334. After becoming members, the Distributors and manufacturers were eligible to participate on councils, committees, task forces and working groups, including the:

a. Industry Relations Council,

b. Business Technology Committee,

c. Logistics Operation Committee,

d. Manufacturer Government Affairs Advisory Committee, and

e. Contracts and Chargebacks Working Group[155]

335. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences to Purdue 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."[156] These conferences provided HDA

[153] Manufacturer Membership Benefits, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.
[154] Manufacturer Membership, Healthcare Distribution Alliance https://www.hda.org/about/membership/manufacturer (last accessed Nov. 26, 2019).
[155] Councils and Committees, Healthcare Distribution Alliance, (accessed on November 12, 2017), https://www.healthcaredistribution.org/about/councils-and-committees
[156] Business and Leadership Conference – Information for Manufacturers, Healthcare Distribution Alliance, (accessed on September 14, 2017),

members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry"[157] and an opportunity for Manufacturing and Distributor Defendants to work together.

336. Distributor Defendants, Purdue, Mallinckrodt, Allergan, and Teva, also coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include the Purdue and the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[158] This coordination in their lobbying further supports an inference that Distributor Defendants and Purdue worked together.

337. The data that reveals and/or confirms the identity of each wrongful opioid distributor is stored in the DEA's confidential ARCOS (Automation of Reports and Consolidated Orders System) database.[159] The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants, but has not been disclosed to the public.

338. Yet, publicly available information confirms that Purdue, Mallinckrodt, Teva, Allergan and the Distributor Defendants funneled far more opioids into Rhode Island than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious

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https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.

[157] *Id*.

[158] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

[159] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

orders. This information, along with the information known only to Purdue and Distributor Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting the Rhode Island.

339. Rhode Island's information and belief rests upon the following facts:

a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

c. manufacturers regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described above;

d. Distributor Defendants together accounted for the majority of opioids distributed in the United States and each plays such a large part in the distribution of opioids that their own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and,

e. Purdue purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.[160]

340. Upon information and belief, Purdue, Mallinckrodt, Teva, Allergan, and the Distributor Defendants engaged in this practice of paying rebates and/or chargebacks to wholesale drug distributors for sales of prescription opioids to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide.

341. Publicly available ARCOS data shows the high volume of oxycodone and other

[160] *See, e.g.,* 2017 Mallinckrodt MOA at 5 (acknowledging that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors).").

opioids distributed to Rhode Island. Distribution of oxycodone into Rhode Island from 2010 to 2016 was 1.4 times the national average. In 2015, the volume of opioids prescribed in Rhode Island amounted to 557 mg MED per person. This is the equivalent to a one week's supply of high dose opioids for each person in the state, and roughly one month's supply of a low dose opioid prescription (for example, 5 mg of hydrocodone dosed 4 times a day) for each Rhode Islander.[161]

342. The high (and relatively higher) volume of opioids prescribed and distributed in Rhode Island should have raised a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

343. In addition, the increase in fatal overdoses from prescription opioids has been widely publicized for years

344. Based upon these red flags, it can be fairly inferred that Distributors, Mallinckrodt, Teva, Allergan, and Purdue had information about suspicious orders that they did not report, and that they failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Rhode Island.

### D. THE DISTRIBUTOR DEFENDANTS, PURDUE, AND MALLINCKRODT HID THEIR LACK OF COPERATION WITH LAW ENORCEMENT AND FALSELY CLAIMED TO BE ACTIVELY WORKING TO PREVENT DIVERSION

345. After being caught failing to comply with their obligations, Distributor Defendants made broad promises to correct their actions and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future" including specific measures delineated in a "Compliance Addendum" to the Settlement. In 2017, McKesson paid

[161] *See* http://opioid.amfar.org/RI

$150 million to resolve yet another investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

346. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others, to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that, "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[162] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[163] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.

347. Along the same lines, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[164] Its website offers assurances that the company's Controlled Substances Monitoring Program ("CSMP") "uses sophisticated algorithms designed to monitor

[162] http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html
[163] http://cardinalhealth.mediaroom.com/valuestatement
[164] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

for suspicious orders, and block the shipment of controlled substances."[165] Defendant McKesson has also 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."[166]

348. These public statements created the false and misleading impression that the Distributer Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

349. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[167]

350. As described in Section IV.A, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of

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[165] https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/pharmaceutical-supply-chain/

[166] 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, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[167] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

351. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

352. Touting the benefits of ADF opioids, Purdue's website posits: "we are acutely aware of the public health risks these powerful medications create … That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse …"[168] Purdue's statement on "Opioids Corporate Responsibility" likewise states that "[f]or many years, Purdue has committed substantial resources to combat opioid abuse by partnering with … communities, law enforcement, and government."[169] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[170]

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[168] Purdue website, *Opioids With Abuse-Deterrent Properties*, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[169] Purdue website, *Opioids Corporate Responsibility*, http://www.purduepharma.com/ news-media/opioids-corporate-responsibility/.

[170] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue worked behind the scenes to push back against law enforcement. (we should keep this sentence only if they did – either they did or they didn't)

353. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

354. Nevertheless, Purdue, despite making numerous detail visits to suspicious prescribers, did not report items of concern. Purdue visited Jerrold Rosenberg more than 300 times and, upon information and belief, did not report him. Furthermore, as discussed above, Purdue continued to detail one prescriber, Bartel Crisafi, 20 more times after he entered into a consent agreement regarding excessive opioid prescribing. Another prescriber, Dennis Moonan, was disciplined for failing to maintain sufficient safeguards against diversion on July 9, 2014, including a bar on taking on any new patients other than hospice patients who might require opioids. Purdue detailed him an additional 48 times since that time, including on one occasion in 2015 when his secretary told the representative they "use a lot of OxyContin."

355. Mallinckrodt, in addition to lacking an adequate system to detect suspicious orders, Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[171]

356. These public statements create the false and misleading impression that

[171] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

Mallinckrodt has rigorously carried out its duty to report suspicious orders and to exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility. The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders and supplied far more opioids than were justified and led to diversion of opioids in Rhode Island and other states. Furthermore, far from trying to address diversion, Mallinckrodt worked to defeat programs and laws designed to prevent diversion through its sponsorship of APA and USPF.

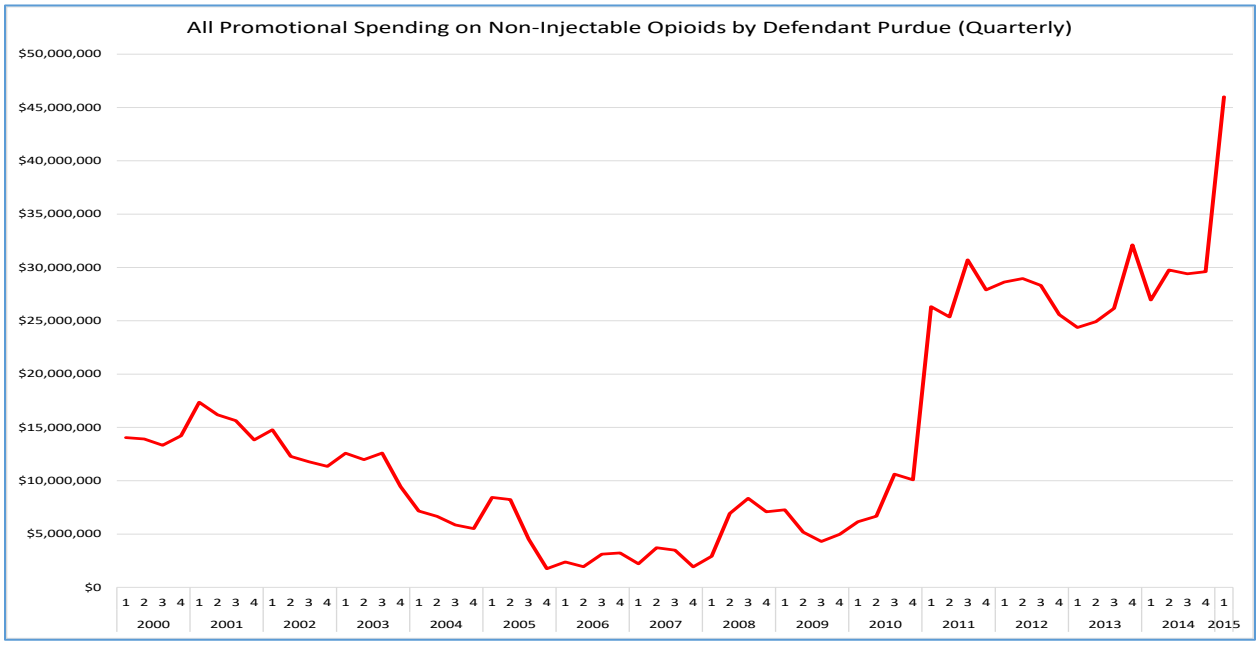
## X. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND CREATED A PUBLIC HEALTH CRISIS SIGNIFICANTLY HARMING RHODE ISLAND AND ITS CITIZENS

357. The deceptive conduct of the Manufacturing Defendants prompted Rhode Island's health care providers to prescribe, patients to take, and, upon information and belief, payors to cover high volumes of opioids for the treatment of chronic pain. Distributor Defendants ensured Rhode Island pharmacies were stocked with opioids. Defendants expanded the prescription opioid market significantly, thereby causing addiction and harm to public health and safety. Purdue itself acknowledged the link between increased opioid prescribing and opioid abuse and diversion; the company's senior medical officials acknowledged in a 2006 in a paper they co-authored, "non-medical use of opioids is a predictable parallel phenomenon of their prescriptive availability and that the extent of diversion is well predicted by the relative potency of the drug and the amount in prescriptive use."[172] While Defendants reaped enormous profits from their scheme, state agencies and most importantly the public has suffered and continues to suffer the

[172] Nabarun Dasgupta, E. Douglas Kramer, Mary-Ann Zalman, Salvatore Carino Jr., Meredith Y. Smith, J. David Haddox, and Curtis Wright IV, "Association between non-medical and prescriptive usage of opioids. *Drug & Alcohol Dependence*, *82*(2), 135-142.

consequences of the opioid epidemic they created.

358. Through its early marketing, Purdue overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Through their continued deceptive conduct, including to the present, Purdue and Insys have both benefited from and extended their prior misrepresentations, sustaining and expanding a market for their opioids. Distributor Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many



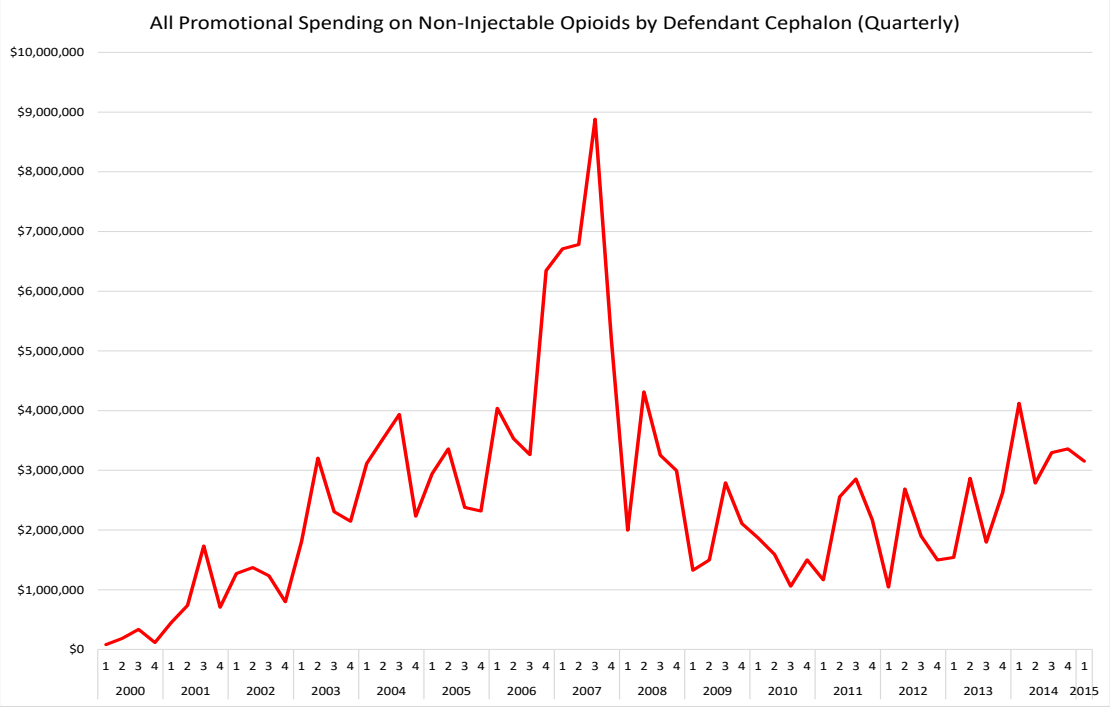

opioids into the state that they could only have been delivering opioids for diversion and illicit use. The opioids that were prescribed, distributed, and used throughout Rhode Island as a result of Defendants' wrongful conduct have devastated Rhode Island and its residents.

359. Purdue deceptive conduct substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

360. Purdue spent roughly $15 million per quarter in 2000 on marketing. Its

promotional spending decreased from 2000 to 2007, as the company came under investigation by the U.S. Department of Justice and various state attorneys general. But by 2010, with the introduction of Butrans and reformulated OxyContin, Purdue ramped up its marketing once again. In 2011, Purdue's marketing spiked to more than $25 million per quarter, and by the end of 2015, with the introduction of Hysingla ER, it soared to more than $40 million per quarter.

361. Teva's quarterly promotional spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:




362. Within Rhode Island, from 2006 through 2017, Purdue made over 42,000 visits to over 1,500 different prescribers, some over 300 times. Insys also spent hundreds of thousands of dollars on promotion in Rhode Island, including direct inducements to one prescriber, Dr.

Rosenberg, to prescribe its drug, as discussed, *supra*. Teva and Mallinckrodt promoted opioids in Rhode Island as well, though less extensively.

363. Numerous prescribers who participated in Rhode Island's Medical Assistance Programs wrote prescriptions as a result of hearing misrepresentations from Purdue or Insys. The following examples of prescribers' are representative claims reimbursed by the Medical Assistance Program following the receipt of misrepresentations:

a. Rhode Island Prescriber A, an internist in Pawtucket, received misrepresentations relating to pseudoaddiction from a sales representative on February 4, 2009. Rhode Island Prescriber A subsequently wrote 10 prescriptions for OxyContin resulting in $2,173.34 in charges to the Medical Assistance Program.

b. Rhode Island Prescriber B, a urologist in Wakefield, received materials from a Purdue sales representative containing misrepresentations about pseudoaddction on February 13, 2009. Rhode Island Prescriber B subsequently wrote 7 prescriptions for OxyContin resulting in $4,253.76 in charges to the Medical Assistance Program.

c. Rhode Island Prescriber C, an internist in Smithfield, received misrepresentations from a Purdue sales representative concerning the superiority of long acting opioids in July 2007. Rhode Island Prescriber C subsequently wrote 88 prescriptions for OxyContin resulting in $66,402.32 in charges to the Medical Assistance Program.

d. Rhode Island Prescriber D, a neurologist in Woonsocket, received misrepresentations from Purdue sales representatives concerning the efficacy of its abuse-deterrent opioids. Rhode Island Prescriber D subsequently wrote 13 prescriptions for OxyContin resulting in $3,766.55 in charges to the Medical Assistance Program.

e. Rhode Island Prescriber E, an orthopedist in Cranston, received misrepresentations from Purdue sales representatives concerning the efficacy of its abuse-deterrent opioids. Rhode Island Prescriber D subsequently wrote 2 prescriptions for OxyContin resulting in $247.79 in charges to the Medical Assistance Program.

364. As a result of this marketing, overall sales of opioids in Rhode Island have also

skyrocketed. From 2007 through 2018, Purdue Schedule II and III opioid drugs cost the Rhode Island Medical Assistance Program $7,236,034.95, representing 19,263 unique prescriptions. Rhode Island's Medical Assistance Program spent $194,685.30 for 27 Subsys prescriptions from May 23, 2014 through March 4, 2016; $176,658.78 of these prescriptions were written by Dr. Rosenberg. These figures do not include the additional expenses paid by the State's employee health plan and workers compensation programs, private third-party payors, and consumers.

365. Government experts have recognized the relationship between the marketing of opioids and increased prescribing and use. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[173]

366. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors … [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[174]

367. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic

[173] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.
[174] *See* n.9, *supra*.

exposure to opioid analgesics, as measured by prescriptions filled, and their abuse,"[175] with particularly compelling data for extended release oxycodone—*i.e.*, OxyContin.

368. 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."[176] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[177]

369. As of 2014, in Rhode Island, almost 5% of the population self-reported using opioids non-medically, exceeding the national average. The percent of the population reporting drug dependence also exceeded the national average, with 3.5% of the State's residents acknowledging a substance abuse order, versus 2.7% nationwide.[178] Analysis of private insurance claims shows that Rhode Island was one of the five states with the greatest proportion of opioid abuse and dependence claims to total medical claims in the nation.[179] This coincides with the fact that, from 2006 through 2013, Rhode Island's per capita prescribing also exceeded the national average.

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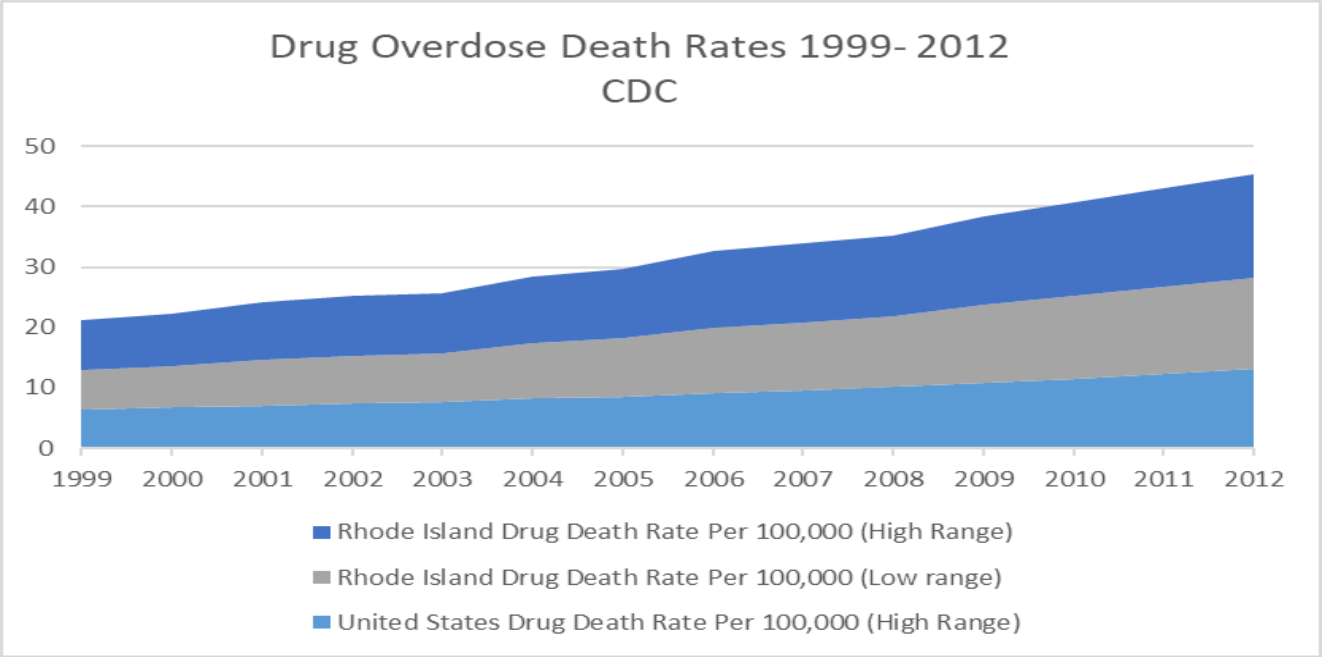
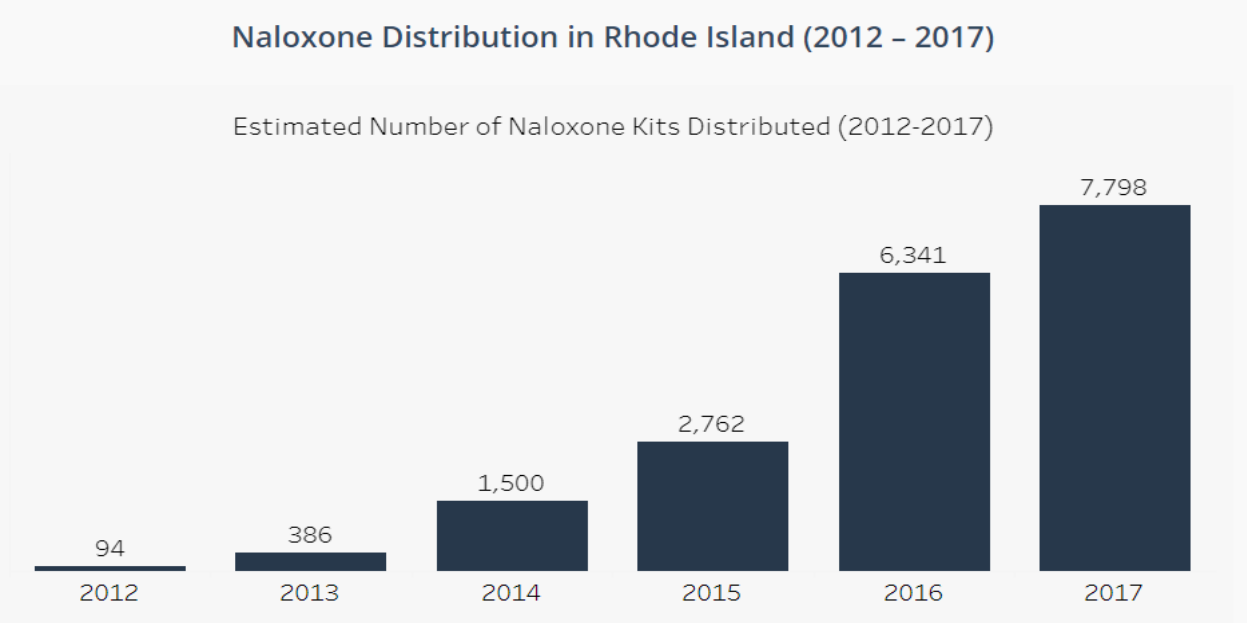
[175] Theodore J Cicero *et al*., *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).
[176] Dart, MD, et al., Trends in Opioid Analgesic Abuse and Mortality in the United States, New Engl. J. Med., 372:241-248 (January 15, 2015).
[177] Califf, MD, et al., A Proactive Response to Prescription Opioid Abuse, New Engl. J. Med. (April 14, 2016).
[178] http://opioid.amfar.org/RI
[179] Alessandra Malito, *The unfortunate thing West Virginia, California and Rhode Island have in common,* Marketwatch (Oct. 1, 2018), https://www.marketwatch.com/story/the-unfortunate-thing-west-virginia-california-and-rhode-island-have-in-common-2018-10-01?link=MW_latest_news




370. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[180]

371. In connection with increases in overdoses and prescription, Rhode Island has drastically increased the numbers of naloxone kits to members of the population at risk, including to opioid users, their kin, and community organizations. Distribution of these kits went from 94 in 2012 to 7,798 in 2017, an increase of more than 8,000%, as set forth below:[181]

[180] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al*. "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.
[181] http://preventoverdoseri.org/naloxone-data/




372. By continuing to fill and failing to report suspicious orders of opioids, Defendant Distributors have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse. Distributor Defendants had financial incentives to distribute higher volumes and not to report suspicious orders or guard against diversion. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in a demand for opioids causing

addiction, a widening demand with an increase in profits, and devastating consequences.[182]

373. "The prescription opioid epidemic and the heroin epidemics are intertwined."[183] Opioids were involved in 42% of all fatal drug overdoses in 2015, and another 25% involved heroin. According to the CDC, between 1999 and 2015, more than 194,000 people died in the United States from prescription-related overdoses. In Rhode Island, annual accidental drug overdoses ranged increased from 111 in 2011 to 336 in 2016. Since 2016, over 60% of drug overdose deaths in Rhode Island have involved fentanyl.

374. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Naloxone—the antidote to opioid overdose.

375. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

376. The use of opioids has caused Rhode Island residents to develop addiction and required treatment often paid for by the State through its Medical Assistance Program and

[182] The Kaiser Family Fund, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (2005), *available at https://www.kff.org/other/report/follow-the-pill-understanding-the-u-s/*

[183] National Academy of Sciences, Pain Management and The Opioid Epidemic, Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, Bonnie, Ford, Phillips, et al., Washington D.C. (2017) at 217.

employee health insurance program. Between 2013 and 2016, the Medical Assistance Program's spending on Suboxone, a drug that treats opioid addiction, more than doubled—from $2.7 million to $6.3 million. Rhode Island's Medical Assistance Program also spent an additional $100,000 on Vivitrol, another opioid addiction drug.

377. Overprescribing and oversupply of opioids has also caused increases in inpatient substance abuse treatment utilization. In 2015, Rhode Island had more than 100 more inpatient stays per 100,000 people compared with the national average. However, four out of every five Rhode Islanders who needed treatment as of 2014 were not receiving it.[184]

378. Since 2017, Rhode Island has spent over $2 million per year to provide medication assisted opioid addiction treatment ("MAT") for incarcerated addicts.

379. There are additional costs from the growing universe of medications aimed at treating other secondary effects of opioids—including not only addiction and overdose, but also other side effects like constipation and sedation. According to a recent analysis by *The Washington Post*, working age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effects medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves. One of the most worrisome effects of opioids has been the spread of Hepatitis C, a serious virus that attacks the kidneys, is transmitted through the sharing of needles used to inject opioids (among other drugs used intravenously). Rhode Island's Medical Assistance Program also spent $18 million on drugs to treat Hepatitis C, including infections, upon information and belief, transmitted through the

[184] See: http://opioid.amfar.org/RI

injection of opioids. In addition, the State has borne the costs of dispensing opioids—in office visits to obtain refills, count pills, or obtain toxicology screens to monitor potential abuse.

380. The deceptive marketing and overprescribing of opioids also had a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse, and adolescent misuse of opioid medications greatly predicts the later use of heroin.[185] However, according to the CDC Guideline, there has been a significant increase in prescribing of opioids to adolescents and children for headaches and injuries.

381. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour. In Rhode Island, the incidence of NAS increased from 2.8 cases per 1,000 in 2002 to 7.3 cases per 1,000 in 2012.

382. Defendants' conduct has also significantly harmed veterans. Sixty percent (60%)

[185] CDC Guideline at 3.

of veterans returning from deployment suffer from chronic pain, double the national average of thirty percent (30%) of U.S. citizens. Veterans are twice as likely to suffer addiction, and to die from opioid abuse than non-veterans according to a 2011 Veterans Administration study.

383. Defendants' success in expanding the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or illicit use and fueled a new wave of addiction, abuse, and injury.

384. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. Upon information and belief, a majority of their patients treated for heroin started their addiction with prescription opioids and then migrated to heroin.

385. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin.[186] Further, 80% of current heroin users began with prescription opioids.[187] The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.[188] A recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid carefully prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Rhode Island's communities. The rise of fentanyl has particularly affected Rhode Island, where it appeared in

[186] CDC Press Release, New Research Reveals the rends and Risk Factors Behind America's Growing Heroin Epidemic, (July 7, 2015)
[187] National Academy of Sciences, Pain Management and The Opioid Epidemic, Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use, Bonnie, Ford, Phillips, et al., Washington D.C. (2017) at 189.
[188] CDC, *Today's Heroin Epidemic*, Vital Signs (available at https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html).

more than *half* of all fatal overdoses in 2016.

## XI. DEFENDANTS FRADULENTLY CONCEALED THEIR MISCONDUCT

386. Defendants, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that prescription opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of this, and likewise, Purdue and paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Manufacturing Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

387. Notwithstanding this knowledge, at all times relevant to this Third Amended Complaint, Manufacturing Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. They disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Purdue hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue masked or never disclosed their role in shaping, editing, and approving the content of this information. Defendants also distorted the meaning or import of studies it cited and offered them as evidence for propositions the

studies did not support. Insys likewise held itself out as a legitimate pharmaceutical company by purporting to hold speaker events in Rhode Island that were in reality shams to induce or reward a specific doctor for continuing to prescribe an addictive drug, including to inappropriate patients who did not benefit from the treatment.

388. Teva fraudulently concealed its conduct by using CME programs as a vehicle for off-label marketing, masking the product-specific promotion of its opioids for chronic pain, even though the "class" of drugs to which its CME pertained could only apply to TIRF drugs.

389. Mallinckrodt, too, disguised its role in the deceptive marketing of chronic opioid therapy by funding and working through unbranded marketing and front groups. In addition, Mallinckrodt affirmatively assured the public, and state and local governments, that it was working to prevent diversion and to curb opioid use and abuse. Yet, it failed to prevent diversion and worked behind the scenes through front groups to undermine programs and statutes designed to combat the epidemic.

390. Manufacturing Defendants thus successfully concealed from the medical community, patients, and the State facts sufficient to arouse suspicion of the claims that Rhode Island now maintains. Rhode Island did not know of the existence or scope of these Defendants' activities and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

391. Distributor Defendants also fraudulently concealed their misconduct. They have declined to release the ARCOS data which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to meet

their obligations to report suspicious orders and prevent diversion. Rhode Island did not know of the existence or scope of the Distributor Defendants' misconduct and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

392. As a result of Defendants' efforts to conceal their misconduct, any statutes of limitation otherwise applicable to any claims asserted herein against all Defendants have been tolled by the discovery rule.

## XII. CAUSES OF ACTION

### COUNT I:
### PUBLIC NUISANCE
### AGAINST THE PURDUE DEFENDANTS, MALLINCKRODT, ALLERGAN, TEVA, AND DISTRIBUTOR DEFENDANTS

393. The State incorporates the preceding paragraphs as if fully set forth herein.

394. A public nuisance is an unreasonable interference with a right common to the general public, such as behavior that unreasonably interferes with the health, safety, peace, comfort or convenience of the general community.

395. Put another way, a public nuisance has been defined as an act or omission which obstructs or causes inconvenience or damage to the public in the exercise of rights common to all.

396. As the Restatement (Second) of Torts explains, "[c]ircumstances that may sustain a holding that an interference with a public right is unreasonable include . . . [w]hether the conduct involves a significant interference with the public health, public safety, the public peace, or the public convenience." *Id.* § 821B at 87.

397. A person or people with control over the instrumentality alleged to have created the nuisance when the damage occurred may be liable for a public nuisance. In other words, one who controls a public nuisance is liable for damages caused by that nuisance.

398. Activities that interfere with a public right, if carried out in violation of state laws or local ordinances, generally have been considered unreasonable interferences.

399. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' conduct, as described in this Third Amended Complaint, unreasonably interferes with a public right, including the health, safety, peace, comfort or convenience of the general community.

400. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' acts and omissions obstruct or cause inconvenience or damage to the public in the exercise of rights common to all.

401. The public nuisance the Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants created and maintained is one that injures the citizens generally who are so circumscribed as to come within its influence.

402. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants knew and should have known that its promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

403. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants knew and should have known that their failure to comply with their statutory and common law duties to maintain effective controls against diversion, including by reporting and exercising due diligence not to fill suspicious orders, would create or assist in the creation or maintenance of a public nuisance.

404. By failing to maintain effective controls against diversion from the closed - system, including by expanding the market for prescription opioids and failing to report and stop

shipment of suspicious orders, the Distributor Defendants, the Purdue Defendants, Mallinckrodt, Allergan, and Teva knowingly exacerbated the opioid crisis in Rhode Island and failed to limit its reach.

405. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants engaged in conduct proscribed by statute, ordinance or administrative regulation, as described in this Third Amended Complaint, including violations of the Rhode Island Controlled Substances Act, R.I. Gen. Laws § 21-28-1.01, *et seq.*, and Administrative Code Section 216—RI ADC 20-20-4.7, which require that manufacturers and distributors maintain "effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and comply with "applicable federal, state, and local law," which also includes the mandates of the Federal Controlled Substances Act set forth in 21 U.S.C. § 823 and 21 C.F.R. 1301.74(b). *See* R.I. Gen. Laws §§ 21-28-3.03 and 3.04.

406. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants willingly participated to a substantial extent in creating and maintaining the public nuisance. Without each Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe.

407. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants had control over their acts and omissions, the instrumentalities causing the public nuisance, at the time the damage occurred. Purdue was in control of the "instrumentality" of the nuisance, namely the process of marketing and the creation and maintenance of the increase in the demand for prescription opioids at all relevant times, which included control of the misleading representations they conveyed through branded and unbranded marketing and

product promotion resulting in the harm caused by the opioid epidemic.

408. The Purdue Defendants, Mallinckrodt, Allergan, and Teva controlled their deceptive marketing schemes and the instrumentalities they used to disseminate their messages and mislead the public, such as detailing by their sales representatives, online communications, publications, CME programs and other speaking events, and other means described in this Third Amended Complaint.

409. The Purdue Defendants, Mallinckrodt, Allergan, and Teva's actions in deceptively and unlawfully marketing opioids were, at the very least, a substantial factor in opioids becoming widely available and widely used and in the public health crisis that followed. Purdue and Insys perpetuated their deceptive advertising campaign and failed to correct their prior misstatements as the damage occurred and continues to occur. Purdue knew as early as 2006 that non-medical use of opioids could be predicted by their relative potency and availability.

410. Likewise, the Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of these Defendants controlled the systems they developed to control against diversion, including the criteria and process they used to identify red flags of suspicious orders or prescribing, whether and to what extent they trained their employees to report and exercise due diligence not to fill such orders or supply such prescribers, whether they intentionally manipulated their systems or ordering process to avoid reporting red flags or declining shipments, and whether they filled orders they knew would expand the use of addictive opioids and knew or should have known were likely to be diverted or fuel an illegal market they created resulting in the harm caused by the opioid epidemic.

411. Distributor Defendants, the Purdue Defendants, Mallinckrodt, Allergan, and Teva were in control of the closed system for the creation and distribution of opioids, upon information and belief deliberately disregarded their duty to prevent diversion by failing to detect, report, and reject suspicious orders for opioids, causing opioids to be widely available for use, abuse, and misuse, fueling a secondary, criminal market for opioids, and magnifying their negative impact on law enforcement and causing harm to the public.

412. The public nuisance caused by prescription opioids is substantial and unreasonable interference with the public health, safety and welfare and has resulted in widespread opioid addiction, abuse, overdose, and death in the State of Rhode Island, with devastating impacts on residents and families, their communities, and government.

413. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' conduct is unreasonable, and unlawful.

414. The Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' conduct in creating and maintaining the public nuisance is ongoing and persistent.

415. Given the nature of opioids, the prior history of addiction and abuse, the importance of a closed system of distribution, and their own monitoring of the use and abuse of opioids, the Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' knew of the public health hazard their conduct would create and was creating in the State and across the country.

416. The public nuisance—i.e., the opioid epidemic—created, perpetuated, maintained and the Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' acts and omissions can be abated and further recurrence of such harm and inconvenience can be abated by (a) educating prescribers (especially primary care physicians and the most prolific

prescribers) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids; (c) retrieving and disposing of excess opioids, eliminating a primary pathway of exposure for adolescents; (d) providing screening and treatment to pregnant women and newborns to reduce the incidence and impact of prenatal exposure; (e) making naloxone widely available so that overdoses are less frequently fatal; and (f) restraining the channels for diverting opioids by appropriately setting and enforcing customer limits, reporting suspicious orders, prescribers, and customers, and stopping, rather than simply delaying, the shipment of suspicious orders, among other measures. the Purdue Defendants, Mallinckrodt, Teva, and the Distributor Defendants' can act to abate the public nuisance, and in certain respects, the law recognizes that they are uniquely well positioned and required to do so.

417. The Purdue Defendants successfully mislead healthcare providers and patients alike, and changed the perception and practices regarding opioids. It is the manufacturer of a drug that has primary responsibility to assure the safety, efficacy, and appropriateness of a drug's labeling, marketing, and promotion. This responsibility exists independent of any FDA regulation, to assure that its products and promotion meet both federal and state consumer protection laws and regulations. *Compare, e.g., Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009) (explaining that "[t]hrough many amendments to the [Food Drug and Cosmetic Act] and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times" and "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market"); *id.* at 578-79 & n. 11 (further stating that "state law actions" continue to "play a critical role in "uncover[ing] unknown drug hazards and provid[ing] incentives for drug

manufacturers to disclose safety risks promptly").

418. The Purdue Defendants, Mallinckrodt, Allergan, Teva, and the Distributor Defendants are also uniquely well positioned to control and stop fueling, and to cut off at the source, diversion of prescription opioids. As registered manufacturers and distributors of controlled substances, Defendants are placed in a position of special trust and responsibility. Because of their direct relationship with customers in the supply chain, they are uniquely capable of determining whether a pharmacy is facilitating the diversion of prescription opioids. Because distributors both handle such large volumes of controlled substances, and are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, their obligation to maintain effective controls to prevent diversion of controlled substances is critical. Manufacturers such as Purdue possessing detailed information about prescribing practices and ordering data purchased from opioid distributors are also positioned to act as a first line of defense.

419. The Purdue Defendants, Mallinckrodt, Allergan, Teva, and the Distributor Defendants' conduct directly and proximately caused injury to the State and its residents.

420. The State has been, and continues to be, injured by the Purdue Defendants, Mallinckrodt, Teva, Allergan, and the Distributor Defendants' actions in creating a public nuisance.

## COUNT II:
## FRAUD AND FRAUDULENT MISREPRESENTATION
## AGAINST DEFENDANTS THE PURDUE DEFENDANTS, INSYS, MALLINCKRODT, ALLERGAN, AND TEVA

421. The State incorporates the preceding paragraphs as if fully set forth herein.

422. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva made false

representations intending thereby to induce patients, healthcare providers, and the State to rely thereon. In addition, the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva intentionally failed to disclose material facts that they had a duty to disclose by virtue of these Defendants' other representations.

423. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids, and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, The Purdue Defendants, Mallinckrodt, Allergan, and Teva engaged in misrepresentations, deception, and knowing omissions of material fact. Purdue also engaged in misrepresentations, deception, and knowing omissions of material fact in falsely promoting abuse-deterrent formulations as reducing abuse, as well as in falsely claiming that OxyContin provides 12 hours of relief.

424. In addition, Insys, by deceptively promoting Subsys as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, misrepresenting the appropriateness of Subsys for treating those conditions, and implementing a kickback scheme wherein it paid prescribers for sham speakers programs in exchange for prescribing Subsys and an insurance fraud scheme through which information about patients was misrepresented, engaged in misrepresentations, deception, and knowing omissions of material fact.

425. Teva, by promoting Actiq and Fentora as safe and appropriate for uses such as neck and back pain, without disclosing the lack of approval or evidence for such uses, and misrepresenting the appropriateness of Actiq and Fentora for treating those conditions, engaged in misrepresentations, deception, and knowing omissions of material fact.

426. Specifically, misrepresentations or omissions include, but are not limited to, those set forth above.

427. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva knew at the time that they made their misrepresentations and omissions that they were false.

428. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva intended that the State and its prescribers, patients, and payors would rely on their misrepresentations and omissions, and that such reliance would cause the State to suffer loss.

429. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva's misrepresentations and omissions in this regard were made with the intention and effect of inducing the State to pay for or reimburse the costs of using opioids to treat chronic pain and to prescribe Subsys instead of other medications, with reckless disregard for the costs the State would incur as a direct and proximate result, including the costs of treating addiction and implementing programs to mitigate or reverse the public health epidemic.

430. The State justifiably relied on the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva's misrepresentations and omissions of material fact, to its damage.

431. The Purdue Defendants identified many prescribers engaged in suspicious prescribing of its opioids, but failed to report its suspicions, as required by law, and failed to stop filling the prescriptions of prescribers it suspected of illegal activity with more drugs, while claiming to be activity working to curb the opioid epidemic.

432. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva knew, or should have known, that as an inevitable consequence of the conduct described herein, Rhode Island citizens would suffer opioid addiction, overdose, death, and associated economic and other loss, and the State would likewise suffer economic and other loss. Further, The Purdue Defendants

and Mallinckrodt knew, or should have known, that its failure to report suspicious prescribing or stop the supply of its drugs to these providers has resulted in continued illicit prescribing of opioids by prescribers who could have been investigated and stopped.

433. In addition, the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva's false representations and concealments were reasonably calculated to deceive the State and health care providers who treated patients whose care was paid for or reimbursed by the State and the patients who received the care and the State in paying for or reimbursing that care.

434. Prescribers, patients, and the State justifiably relied to their determinant on Purdue's and Insys's misrepresentations and concealment of material fact.

435. But for the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva misrepresentation and concealment of material facts, the State would not have incurred damages in paying for medically unnecessary prescriptions and in addressing the public health crisis that the Purdue Defendants', Insys's, Mallinckrodt's, Allergan, and Teva's actions have created.

436. As a direct and proximate result of the Purdue Defendants', Insys's, Mallinckrodt's, Allergan, and Teva's s acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Third Amended Complaint.

437. Defendants acted, intentionally, recklessly, or with malice or willful and wanton disregard for others, justifying an award of punitive damages.

**COUNT III:**
**NEGLIGENCE/NEGLIGENCE PER SE/GROSS NEGLIGENCE AND NEGLIGENT MISREPRESENTATION**
**AGAINST ALL DEFENDANTS**

438. The State incorporates the preceding paragraphs as if fully set forth herein.

439. Defendants have a duty to exercise reasonable care in manufacturing, marketing,

selling, and distributing highly dangerous opioid drugs in Rhode Island.

440. Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

441. Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility *vis a vis* Plaintiffs. Their duty cannot be delegated.

442. In addition, R.I. Gen. Laws §§ 21-28-3.04 and 21-28-3.28, and 216—RI ADC 20-20-4.7, which require that manufacturers and distributors satisfy registration and licensing requirements mandating that they "maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels" and comply with "applicable federal, state, and local law" are public safety laws. Each Defendant had a duty under, *inter alia,* these laws to maintain effective controls against diversion of prescription opioids to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

443. Defendants also had a duty under the Federal Controlled Substances Act ("CSA") and its implementing regulations, incorporated through the Rhode Island laws listed above, to report suspicious prescribing and dispensing and to maintain systems to detect and report such activity.

444. Upon information and belief, each of the Defendants repeatedly and intentionally breached its duties.

445. The foreseeable harm from a breach of these duties is the sale, use, abuse, and

diversion of prescription opioids.

446. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the State.

447. 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. Indeed, it is a violation of R.I. Gen. Laws §§ 21-28-3.03 and 21-28-3.28, and 216—RI ADC 20-20-4.7 for Defendants not to exercise due diligence not to ship suspicious orders unless they report such orders as required under the CSA. Defendants have a duty to maintain effective controls against diversion. 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 to prevent precisely these types of harms.

448. 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 and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Purdue Defendants, Insys, Mallinckrodt, and Teva. Reasonably prudent manufacturers would know that failing to report suspicious prescribing, or paying kickbacks or engaging in deceptive and unlawful practices to encourage and permit overprescribing, particularly while assuring the public of a commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

449. Reasonably prudent manufacturers and distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur. Reasonably prudent manufacturers and distributors would also know that if they filled orders likely fuel diversion, that law enforcement would not catch and stop all diversion from such orders before harm had already occurred, and would be even less likely to do so given Defendants' misrepresentations regarding their compliance with their minimum legal obligations and voluntary commitment to exceeding those obligations.

450. Defendants acted, intentionally, recklessly, or with malice or willful and wanton disregard for others in breaching their duties, justifying an award of punitive damages. Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the State.

451. In addition, the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva, in the course of their business, profession or employment, or in any other transaction in which they had a pecuniary interest, supplied false information for the guidance of others in their business transactions and failed to exercise reasonable care or competence in obtaining or communicating the information.

452. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva had a duty to the State and its residents to exercise due care in the advertising, marketing, promotion, and sale of opioid drugs.

453. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva had a duty to the State and its residents not to make false, misleading, or deceptive statements about opioids and

treatment for chronic pain.

454. Insys had a duty to the State not to make false, misleading, or deceptive statements about the use of Subsys and the patients Subsys was being used to treat.

455. Teva had a duty to the State not to make false, misleading, or deceptive statements about the use of Actiq and Fentora and the patients Actiq and Fentora were being used to treat.

456. The Purdue Defendants, Teva, Allergan, and Mallinckrodt had a duty to the State and its residents to report suspicious prescribers and to refrain from providing opioids to providers and pharmacies it believed, or had reason to believe, were dispensing its opioids illegally, as well as a duty not to misrepresent its commitment to adhering to this obligation.

457. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva knew or should have known that they breached the duties described above.

458. The Purdue Defendants', Insys's, Mallinckrodt's, Allergan, and Teva's misrepresentations, omissions, and carelessness in this regard was done with the intention and effect of inducing the State to pay for or reimburse the costs of using opioids to treat chronic pain and of using Subsys, Actiq, and Fentora for conditions for which they were not medically necessary, approved or shown to be effective, and with reckless disregard for the costs the State would incur as a direct and proximate result, including the costs of treating addiction and implementing programs to mitigate or reverse the prevalence of opioid addiction in Rhode Island.

459. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva knew, or should have known, that prescribers, patients, and State programs would rely on its misrepresentations and deceptive statements, and would be misled by their material omissions.

460. The Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva knew, or should have known, that as an inevitable consequence of the conduct described herein, Rhode Island citizens would suffer opioid addiction, overdose, death, and associated economic loss, and the State would suffer.

461. Prescribers, patients, and the State relied to their determinant on the Purdue Defendants, Insys, Mallinckrodt, and Teva's misrepresentations and concealment of material fact.

462. But for the Purdue Defendants', Insys's, Mallinckrodt's, Allergan, and Teva's misrepresentation and concealment of material facts, the State would not have incurred damages in paying for medically unnecessary prescriptions and in addressing the public health crisis that the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva's actions have created.

463. As a direct and proximate result of the Purdue Defendants', Insys's, Mallinckrodt's, Allergan, and Teva's acts and omissions as alleged herein, the State has sustained and will sustain substantial expenses and damages, described in this Third Amended Complaint.

464. Defendants acted, intentionally, recklessly, or with malice or willful and wanton disregard for others in breaching their duties, justifying an award of punitive damages.

**COUNT IV:**
**UNJUST ENRICHMENT**
**AGAINST ALL DEFENDANTS**

465. The State incorporates the preceding paragraphs as if fully set forth herein.

466. As an expected and intended result of their conscious wrongdoing as set forth in this Third Amended Complaint, the Purdue Defendants, Insys, Mallinckrodt, Allergan, and Teva have profited and benefited from opioid purchases made by the State.

467. In exchange for the opioid purchases, and at the time the State made these

payments, the State expected that Defendants had not engaged in deceptive practices or practices contrary to the State's public policy and causing the State to suffer a public health epidemic, as well as that Defendants had not misrepresented any material facts.

468. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, the Purdue Defendants, Mallinckrodt, Allergan, and Teva have unjustly enriched themselves at the State's expense. By Insys illegally and deceptively promoting Subsys, and by Teva illegally and deceptively promoting Actiq and Fentora for conditions for which they were not shown to be effective or approved; and by Insys's paying kickbacks and engaging in a scheme to misrepresent patient information for purposes of obtaining kickback, the State has made payments for opioid prescriptions, Insys and Teva benefited from those payments. Because of their deceptive promotion of opioids, the Purdue Defendants, Insys, Mallinckdot, Allergan, and Teva obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the State lacks a remedy provided by law.

469. Further, as an expected and intended result of their conscious wrongdoing as set forth in this Third Amended Complaint, all Defendants each have profited and benefited from the increase in the distribution and purchase of opioids within the State

470. The State has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

471. These expenditures include the provision of healthcare services and treatment services to people who use opioids among others.

472. These expenditures have helped sustain Defendants' businesses.

473. The State has conferred a benefit upon Defendants by paying for Defendants'

externalities: the cost of the harms caused by Defendants' improper distribution practices.

474. Upon information and belief, the State has also conferred a benefit upon Defendants by paying for purchases by unauthorized users of prescription opioids from the Defendants' supply chain for non-medical purposes.

475. The Defendants knew that they were receiving a benefit from the State's payment of Defendants' externalities and, upon information and belief, payment for purchases by unauthorized users of prescription opioids.

476. By distributing a large volume of opioids within the State and by acting in concert with third parties, Defendants have unjustly enriched themselves at the State's expense. The State has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the State lacks a remedy provided by law.

477. Defendants have unjustly retained a benefit to the State's detriment, and these Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

## XIII. PRAYER FOR RELIEF

WHEREFORE, the State prays for judgment against Defendants as permitted by Rhode Island law, as follows:

a. A finding that, by the acts alleged herein, the Purdue Defendants, Mallinckrodt, Allergan, Teva, and the Distributor Defendants have created a public nuisance;

b. An injunction permanently enjoining Defendants from engaging in the acts and practices that violated Rhode Island laws;

c. An order directing the Purdue Defendants, Mallinckrodt, Allergan, Teva, and the Distributor Defendants to abate and pay damages for the public nuisance;

d. For a declaration that Purdue Defendants, Allergan, Teva, Mallinckrodt, and Insys have engaged in fraud and fraudulent misrepresentation; and that all Defendants are liable for negligence, and unjust enrichment;

e. Compensatory damages sufficient to fairly and completely compensate for all damages alleged herein;

f. Punitive damages;

g. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

h. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

i. For all other relief at law or in equity, deemed just by this Court.

Dated: March 22, 2022

**State of Rhode Island,**
By Peter F. Neronha, Attorney General

*/s/ Etie-Lee Schaub*

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