

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ORANGE

Civil Complex Center
751 W. Santa Ana Blvd
Santa Ana, CA 92701

SHORT TITLE: The People of the State of California, acting by and through Santa Clara County Counsel Orry P. Korb and Orange County District Attorney Tony Rackauckas vs. Purdue Pharma L.P.

CLERK'S CERTIFICATE OF MAILING/ELECTRONIC SERVICE

CASE NUMBER:
30-2014-00725287-CU-BT-CXC

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NOV 01 2021

DAVID H. YAMASAKI, Clerk of the Court

BY: _____, DEPUTY

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ORANGE

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7 THE PEOPLE OF THE STATE OF
8 CALIFORNIA, acting by and through Santa
9 Clara County Counsel James R. Williams,
10 Orange County District Attorney Tony
11 Rackauckas, Los Angeles County Counsel
12 Mary C. Wickham, and Oakland City Attorney
13 Barbara J. Parker,

Plaintiffs,

v.

14 PURDUE PHARMA L.P.; PURDUE
15 PHARMA INC.; THE PURDUE FREDERICK
16 COMPANY, INC.; TEVA
17 PHARMACEUTICAL INDUSTRIES, LTD;
18 TEVA PHARMACEUTICALS USA, INC.;
19 CEPHALON, INC.; JOHNSON & JOHNSON;
20 JANSSEN PHARMACEUTICALS, INC.;
21 ORTHO-MCNEIL-JANSSEN
22 PHARMACEUTICALS, INC. n/k/a JANSSEN
23 PHARMACEUTICALS, INC.;
24 JANSSEN PHARMACEUTICA, INC. n/k/a
25 JANSSEN PHARMACEUTICALS, INC.;
26 ENDO HEALTH SOLUTIONS INC.; ENDO
27 PHARMACEUTICALS, INC.; ACTAVIS
28 PLC; ACTAVIS, INC.; WATSON,
PHARMACEUTICALS, INC. n/k/a
ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS LLC; and
ACTAVIS PHARMA, INC. f/k/a WATSON
PHARMA, INC.,

Defendants.

Case No. 30-2014-00725287-CU-BT-CXC

Judge: Honorable Peter J. Wilson
Dept.: CX102

Action Filed: May 21, 2014
Trial Date (Phase I): April 19, 2021

TENTATIVE DECISION

1 I. Introduction

2 This Court is aware of the toll being taken on society by what has been
3 variously referred to as the “opioid crisis” or the “opioid epidemic.” See, for example,
4 *City and County of San Francisco v. Purdue Pharma LP* 491 F.Supp.3d 610, 629.
5 Drug abuse, including opioid abuse, affects not only the individuals directly
6 involved, but their family and friends, doctors and other medical care providers,
7 emergency rooms, law enforcement, and indeed all those impacted at each step of
8 the drug-abuse cycle. Opioid-related hospitalization rates and opioid-related deaths
9 starkly demonstrate the enormity of the on-going problem.

10 Defendants do not dispute that there is an opioid crisis.

11 What Defendants dispute is whether Plaintiffs have proven that the opioid
12 crisis constitutes an actionable public nuisance for which Defendants, or any of
13 them, are legally liable.

14 The Court’s findings and conclusions address the question of liability based
15 on the evidence in this trial, and are in no manner intended to ignore or minimize
16 the existence and extent of the ongoing opioid crisis.

17 II. The Pleadings and Parties, Phase I Trial

18 Plaintiffs commenced this action by filing their Complaint on May 21, 2014.
19 Plaintiffs are the People of the State of California, acting by and through Santa
20 Clara County Counsel, Orange County District Attorney, Los Angeles County
21 Counsel, and the Oakland City Attorney. (Santa Clara County, Orange County, Los
22 Angeles County and the City of Oakland are together referred to as the "Plaintiff
23 Jurisdictions.")

24 The operative complaint is the Sixth Amended Complaint filed June 8, 2018.
25 The Sixth Amended Complaint asserts causes of action for False Advertising
26 (Business and Professions Code Sections 17500 *et seq*), Unfair Competition (Business
27 and Professions Code Section 17200 *et seq*), and Public Nuisance (California Civil
28 Code Sections 3479 and 3480).

1 In summary, Plaintiffs contend that each Defendant engaged in an aggressive
2 false and/or misleading marketing scheme designed to increase, and which
3 succeeded in increasing, the writing of prescriptions for Defendants' opioid
4 medications, and that the increased prescriptions have caused or contributed to the
5 opioid crisis (defined more fully below) being experienced in California, including in
6 the Plaintiff Jurisdictions. The opioid crisis constitutes the public nuisance which
7 Plaintiffs seek to abate in their third cause of action. The alleged false and/or
8 misleading marketing constitutes the false advertising which forms the basis for the
9 first and second causes of action.

10 Phase I of this case regarding liability was tried to the Court between April
11 19, 2021 and July 27, 2021 . No party requested trial by jury on any claim or issue.
12 The entire trial was conducted remotely, via the Zoom platform.

13 Defendants at trial were Johnson & Johnson, Janssen Pharmaceuticals, Inc.,
14 Ortho-McNeil Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.,
15 Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc. (collectively the
16 "Janssen Defendants"), Endo Pharmaceuticals Inc., Endo Health Solutions Inc.
17 (collectively the "Endo Defendants"), Allergan plc, Allergan Finance, LLC
18 (collectively the "Allergan Defendants"), Cephalon, Inc., Teva Pharmaceuticals USA,
19 Inc., Actavis LLC (collectively the "Teva Defendants"), Actavis Pharma, Inc., and
20 Watson Laboratories, Inc.¹

21 The People rested their case in chief on June 2, 2021. Defendants thereafter
22 filed motions for judgment pursuant to CCP section 631.8. After full briefing on the
23 motions, and oral argument, the Court declined to render judgment until the close of
24 all the evidence in the case. Defendants then put on their respective cases, followed
25 by Plaintiffs' rebuttal.

26 ¹ Actavis Pharma, Inc., and Watson Laboratories, Inc. were dismissed with prejudice
27 by Plaintiffs after Plaintiffs rested their case in chief.

28 All proceedings against named defendants Purdue Pharma L.P., Purdue Pharma Inc.
and The Purdue Frederick Company, Inc. have been stayed by reason of a bankruptcy filing.

1 The parties called witnesses and introduced various exhibits into evidence.
2 Witness testimony was also introduced by written and videotaped depositions. The
3 parties also stipulated to various facts, and party-admissions were admitted and
4 read into the record.

5 All parties rested on July 27, 2021.

6 The Court set a briefing schedule for closing briefs, and closing arguments
7 were heard on September 30, 2021 and October 1, 2021.

8 Having received and considered the parties' respective briefs, having heard
9 the closing arguments and having considered the evidence and the law, the Court
10 now issues its Tentative Decision.

11 There is no dispute that the burden of proof as to the allegations of the Sixth
12 Amended Complaint is on Plaintiffs, and that Plaintiffs' burden is to be discharged
13 by a preponderance of the evidence.

14 III. The Claims Asserted

15 A. First Cause of Action - False Advertising ("FAL")

16 Bus. & Prof. Code, § 17500 provides, in relevant part, as follows:

17 "It is unlawful for any person . . . corporation . . . or any employee
18 thereof with intent directly or indirectly to dispose of real or personal property
19 or to perform services . . . or to induce the public to enter into any obligation
20 relating thereto, to make or disseminate or cause to be made or disseminated
21 before the public in this state . . . in any newspaper or other publication, or
22 any advertising device . . . or in any other manner or means
23 whatever, including over the Internet, any statement, concerning that real or
24 personal property or those services . . . which is untrue or misleading, and
25 which is known, or which by the exercise of reasonable care should be known,
26 to be untrue or misleading . . ."

27 And as relevant to the standing of Plaintiffs to assert this claim, Bus. & Prof.
28 Code, § 17536 provides in relevant part that:

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“(a) Any person who violates any provision of this chapter shall be liable for a civil penalty not to exceed two thousand five hundred dollars (\$2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General or by any district attorney, county counsel, or city attorney in any court of competent jurisdiction.”

B. Second Cause of Action – Unlawful Business Practices (“UCL”)
Bus. & Prof. Code, § 17200 provides, in relevant part, as follows:

“As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1.”

Section 17206 provides in relevant part as follows:

“(a) Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty not to exceed two thousand five hundred dollars (\$2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California by the Attorney General, by any district attorney, by any county counsel . . .”

C. Third Cause of Action - Public Nuisance
Civil Code section 3479 provides, in relevant part, as follows.

“Anything which is injurious to health, including, but not limited to, the illegal sale of controlled substances, or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property . . . is a nuisance.”

1 Section 3480 provides as follows:

2 "A public nuisance is one which affects at the same time an entire
3 community or neighborhood, or any considerable number of persons, although
4 the extent of the annoyance or damage inflicted upon individuals may be
5 unequal."

6 Section 3482 provides as follows:

7 "Nothing which is done or maintained under the express authority of a
8 statute can be deemed a nuisance."

9
10 IV. Discussion and Findings

11 A. Public Nuisance

12 In *People v. ConAgra Grocery Products Co.* (2017) 17 Cal.App.5th 51, a case
13 extensively relied upon by Plaintiffs, the Court of Appeal set forth critical aspects of
14 the law on public nuisance as follows:

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16 "A public nuisance cause of action is established by proof that a
17 defendant knowingly created or assisted in the creation of a substantial
18 and unreasonable interference with a public right. (*Santa Clara*
19 *I, supra*, 137 Cal.App.4th at pp. 305-306, 40 Cal.Rptr.3d 313.)"

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21 "Causation is an element of a cause of action for public nuisance.
22 (*Melton v. Boustred* (2010) 183 Cal.App.4th 521, 542, 107 Cal.Rptr.3d
23 481.) "A connecting element to the prohibited harm must be shown." (*In*
24 *re Firearm Cases* (2005) 126 Cal.App.4th 959, 988, 24 Cal.Rptr.3d 659
25 (*Firearm Cases*)). The parties agree that the causation element of a
26 public nuisance cause of action is satisfied if the conduct of a defendant
27 is a substantial factor in bringing about the result. (*Citizens for Odor*
28 *Nuisance Abatement v. City of San Diego* (2017) 8 Cal.App.5th 350, 359,

1 213 Cal.Rptr.3d 538 [applying substantial factor standard in a public
2 nuisance action].) “The substantial factor standard is a relatively
3 broad one, requiring only that the contribution of the individual cause
4 be more than negligible or theoretical.’ [Citation.] Thus, ‘a force which
5 plays only an “infinitesimal” or “theoretical” part in bringing about
6 injury, damage, or loss is not a substantial factor’ [citation], but a very
7 minor force that does cause harm is a substantial factor [citation].”
8 (*Bockrath v. Aldrich Chemical Co., Inc.* (1999) 21 Cal.4th 71, 79, 86
9 Cal.Rptr.2d 846, 980 P.2d 398.)”

10
11 “‘*Anything* which is injurious to health ... or is indecent or offensive to
12 the senses, or an obstruction to the free use of property, so as to
13 interfere with the comfortable enjoyment of life or property . . . is a
14 nuisance.’ (Civ. Code, § 3479, italics added.) ‘A *public* nuisance is one
15 which affects at the same time an entire community or neighborhood,
16 or any considerable number of persons, although the extent of the
17 annoyance or damage inflicted upon individuals may be unequal.’ (Civ.
18 Code, § 3480[, italics added].) ... [¶] ‘*P*ublic nuisances are offenses
19 against, or interferences with, the exercise of *rights common to the*
20 *public.*’ (*People ex rel. Gallo v. Acuna* (1997) 14 Cal.4th 1090, 1103 [60
21 Cal.Rptr.2d 277, 929 P.2d 596], [first italics added].) ‘Of course, not
22 every interference with collective social interests constitutes a public
23 nuisance. To qualify, and thus be enjoined [or abatable], the
24 interference must be both *substantial* and *unreasonable.*’ ([*Id.* at p.
25 1105 [60 Cal.Rptr.2d 277, 929 P.2d 596]].) It is substantial if it causes
26 significant harm and unreasonable if its social utility is outweighed by
27 the gravity of the harm inflicted. ([*Ibid.*].) (*Santa Clara I, supra*, 137
28 Cal.App.4th at p. 305, 40 Cal.Rptr.3d 313.)”

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2 *ConAgra* 17 Cal.App.5th at 79, 101-102, 111-112.
3

4 1. Summary of Findings – Public Nuisance

5 There is no dispute that the “interference with collective social interests”
6 caused by the abuse of opioids is “substantial.”

7 Civil Code sections 3479, 3480 and 3482, and applicable case law, further
8 require that Plaintiffs prove (1) that one or more of the Defendants’ alleged
9 contribution to the interference was “unreasonable” in that the social utility of the
10 conduct constituting the interference is outweighed by the gravity of the harm
11 inflicted, and (2) that the contribution of that Defendant was more than “negligible
12 or theoretical.” *Id.*

13 As explained more fully below, Plaintiffs have failed to prove the element of
14 “unreasonable” interference as defined in *ConAgra* and other cases. And, even
15 assuming some unreasonable interference by one or more of Defendants, Plaintiffs
16 have failed to prove that any such alleged interference was more than “negligible or
17 theoretical.”

18 2. Plaintiffs Have Failed to Prove The “Unreasonable” Element of
19 Public Nuisance

20 As already noted, while there is some disagreement between the parties about
21 a precise definition and scope, there is no dispute that there has been and continues
22 to be an “opioid crisis” in the country, in California, and in the Plaintiff
23 Jurisdictions. (The People define it as a “multifaceted opioid crisis.” Proposed
24 Statement of Decision 1:16. The Allergan Defendants note that “opioid abuse is a
25 significant societal problem.” Post Trial Brief 1:2. The Janssen Defendant note that
26 “The abuse and misuse of opioids are serious public health issues and have
27 disrupted lives and communities in California and elsewhere.” Brief in Response
28 1:14-16. Cephalon, Inc., Teva Pharmaceuticals and Actavis LLC note the “California

1 opioid epidemic.” Post Trial Brief 28:17, 26-27. And the Endo defendants note the
2 “opioid crisis.” Proposed Statement of Decision 52:8.)

3 The evidence has shown, and the Court finds, that each of the Plaintiff
4 Jurisdictions is dealing, to varying degrees, with an opioid crisis that includes
5 Opioid Use Disorder (“addiction”), misuse, overdose and death.

6 The evidence further establishes all of the following:

7 1. All of Defendants’ opioid products at issue here are Schedule II
8 controlled substances under the Controlled Substances Act, 21 U.S.C. § 812 .
9 Schedule II drugs carry “a high potential for abuse” and can “lead to severe
10 psychological or physical dependence.” 21 U.S.C. § 812(b)(2)(A), (C). (As stated
11 in full: “(2) SCHEDULE II. (A) The drug or other substance has a high
12 potential for abuse. (B) The drug or other substance has a currently accepted
13 medical use in treatment in the United States or a currently accepted medical
14 use with severe restrictions. (C) Abuse of the drug or other substances may
15 lead to severe psychological or physical dependence.”)

16 2. There are patients for whom prescription opioids are medically
17 appropriate.

18 3. A person can get addicted to opioids even if the person takes
19 them as prescribed by their doctor.

20 4. There is a direct correlation between an increase in opioid
21 prescriptions and the frequency of misuse, abuse, overdose, and drug related
22 fatalities.

23 5. There is a direct correlation between increased dose and duration
24 of opioid prescriptions and the frequency of misuse, abuse, overdose, and drug
25 related fatalities.

26 6. The facts stated in paragraphs 1 through 5 above have at all
27 material times been known to the Food and Drug Administration (“FDA”), the
28 California Legislature and each of the Defendants.

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3 As obviously follows from paragraph 1 above, the Federal government,
4 through the FDA and the Drug Enforcement Administration (“DEA”), at all material
5 times approved the Defendants’ respective opioid medications, for their approved
6 uses. It did so cognizant of the risks, but having made the determination that the
7 benefits of these medications outweighed their risks. Stated differently, the Federal
8 government made a determination that the “social utility” of appropriately
9 prescribed opioids outweighed the “gravity of the harm inflicted” by them. *ConAgra*
10 at 79, 111-112. (“The statutory standard for FDA approval of a product is that the
11 product is safe and effective for its labeled indications under its labeled conditions of
12 use . . . FDA's determination that a product is safe, however, does not suggest an
13 absence of risk. Rather, a product is considered to be safe if the clinical significance
14 and probability of its beneficial effects outweigh the likelihood and medical
15 importance of its harmful or undesirable effects. In other words, a product is
16 considered safe if it has an appropriate benefit-risk balance for the intended
17 population and use . . . Thus, assessment and comparison of a product's benefits and
18 risks is a complicated process that is influenced by a wide range of societal,
19 healthcare, and individualized patient factors.” Ex. TE-CA-700884.0008. (Internal
20 citations omitted.); *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063: “But there
21 is an important distinction between prescription drugs and other products . . . In
22 the latter cases, the product is used to make work easier or to provide pleasure,
23 while in the former it may be necessary to alleviate pain and suffering or to sustain
24 life. Moreover, unlike other important medical products (wheelchairs, for example),
25 harm to some users from prescription drugs is unavoidable.”)

26 In turn, the California Legislature saw fit to ensure that opioid medications
27 were available to patients who needed them. The California Legislature adopted a
28 two-pronged approach. First, in passing Business and Professions Code section

1 2241.5 in 1990 and in passing the Pain Patient' Bill of Rights in 1997, it ensured
2 that health care practitioners could, in appropriate circumstances, prescribe opioid
3 medications without risk of discipline. Second, in passing the Pain Patient's Bill of
4 Rights in 1997, it ensured that pain patients would have access to opioid
5 medications where that was medically appropriate.

6 The Pain Patient's Bill of Rights (Health and Safety Code Section 124961,
7 read with 124960), provides, in relevant part, as follows:

8 "124961: Nothing in this section shall be construed to alter any of the
9 provisions set forth in Section 2241.5 of the Business and Professions Code.
10 This section shall be known as the Pain Patient's Bill of Rights.

11 (a) A patient who suffers from severe chronic intractable pain has the
12 option to request or reject the use of any or all modalities in order to relieve
13 his or her pain.

14 (b) A patient who suffers from severe chronic intractable pain has the
15 option to choose opiate medications to relieve that pain without first having to
16 submit to an invasive medical procedure . . . as long as the prescribing
17 physician acts in conformance with the California Intractable Pain Treatment
18 Act, Section 2241.5 of the Business and Professions Code.

19 (c) . . .

20 (d) A physician who uses opiate therapy to relieve severe chronic
21 intractable pain may prescribe a dosage deemed medically necessary to
22 relieve the patient's pain, as long as that prescribing is in conformance with
23 Section 2241.5 of the Business and Professions Code."

24
25 Health & Safety Code § 124960 provides as follows:

26 "The Legislature finds and declares all of the following:

27 (a) The state has a right and duty to control the illegal use of opiate
28

1 drugs.

2 (b) Inadequate treatment of acute and chronic pain originating from
3 cancer or noncancerous conditions is a significant health problem.

4 (c) For some patients, pain management is the single most important
5 treatment a physician can provide.

6 (d) A patient suffering from severe chronic intractable pain should have
7 access to proper treatment of his or her pain.

8 (e) Due to the complexity of their problems, many patients suffering
9 from severe chronic intractable pain may require referral to a physician with
10 expertise in the treatment of severe chronic intractable pain. In some cases,
11 severe chronic intractable pain is best treated by a team of clinicians in order
12 to address the associated physical, psychological, social, and vocational issues.

13 (f) In the hands of knowledgeable, ethical, and experienced pain
14 management practitioners, opiates administered for severe acute pain and
15 severe chronic intractable pain can be safe.

16 (g) Opiates can be an accepted treatment for patients in severe chronic
17 intractable pain who have not obtained relief from any other means of
18 treatment.

19 (h) A patient suffering from severe chronic intractable pain has the
20 option to request or reject the use of any or all modalities to relieve his or her
21 pain.

22 (i) A physician treating a patient who suffers from severe chronic
23 intractable pain may prescribe a dosage deemed medically necessary to
24 relieve pain as long as the prescribing is in conformance with Section 2241.5
25 of the Business and Professions Code.

26 (j) A patient who suffers from severe chronic intractable pain has the
27 option to choose opiate medication for the treatment of the severe chronic
28

1 intractable pain as long as the prescribing is in conformance with Section
2 2241.5 of the Business and Professions Code.

3
4 Business and Professions Code Section 2241.5 provides, in relevant part, as
5 follows:

6 “2241.5. Prescription or administration of dangerous drugs or
7 prescription controlled substances for treatment of pain or condition causing
8 pain

9 (a) A physician and surgeon may prescribe for, or dispense or
10 administer to, a person under his or her treatment for a medical condition
11 dangerous drugs or prescription controlled substances for the treatment of
12 pain or a condition causing pain, including, but not limited to, intractable
13 pain.

14 (b) No physician and surgeon shall be subject to disciplinary action for
15 prescribing, dispensing, or administering dangerous drugs or prescription
16 controlled substances in accordance with this section.”

17
18 To avoid Federal preemption issues Plaintiffs have stressed throughout that
19 they are not asking this Court to sit in judgment of the FDA’s approvals of
20 prescription opioids. And, to avoid California safe harbor protections (in particular,
21 Civil Code section 3482 which provides that nothing done under the express
22 authority of a statute can be deemed a nuisance (*supra*)), Plaintiffs have stressed
23 that they are not asking this Court to find a public nuisance based on conduct
24 expressly permitted by law.

25 Mindful of those limiting factors, Plaintiffs nevertheless contend: that neither
26 Federal nor California law precludes a finding of liability based on false or
27 misleading marketing and promotion; that Defendants knew increased opioid
28

1 prescriptions result in increased adverse downstream consequences; and that
2 Defendants' false or misleading marketing and promotion in fact resulted in
3 increased prescriptions, with increased adverse downstream consequences (the
4 "opioid crisis" alleged).

5 Most significantly, Plaintiffs also contend that they need only prove that the
6 number (and/or the dose and duration) of prescriptions increased, without
7 distinguishing between medically appropriate and medically inappropriate
8 prescriptions.

9 The Court disagrees.

10 Specifically, the Court finds that even if any of the marketing which caused
11 an increase in the number, dose or duration of opioid prescriptions *did* include false
12 or misleading marketing, any adverse downstream consequences flowing from
13 *medically appropriate* prescriptions cannot constitute an actionable public nuisance.
14 This is so because, as the Federal government and the California Legislature have
15 already determined, and as this Court finds, the social utility of medically
16 appropriate prescriptions outweighs the gravity of the harm inflicted by them and so
17 is not "unreasonable" or, therefore, enjoined. *ConAgra* at 79, 111-112.

18 Plaintiffs have shown that during the period 1997 (when the Pain Patient's
19 Bill of Rights was passed) through 2011 the volume of opioid prescriptions (in both
20 numbers and dosage) increased dramatically. But the mere proof of a rise in opioid
21 prescriptions does not, without more, prove there was also a rise in medically
22 *inappropriate* opioid prescriptions. Plaintiffs made no effort to distinguish between
23 medically appropriate and medically inappropriate prescriptions. There is simply no
24 evidence to show that the rise in prescriptions was not the result of the medically
25 appropriate provision of pain medications to patients in need. A need the Pain
26 Patient's Bill of Rights and Health and Safety Code section 2241.5 were specifically
27 designed to meet.

28 Plaintiffs proffered *no* evidence that the allegedly false or misleading

1 marketing by Defendants caused the writing of medically inappropriate
2 prescriptions. Instead, Plaintiffs ask the Court to infer that the rise in prescriptions
3 generally must logically also have resulted in the rise of medically inappropriate
4 prescriptions. But there is no evidence, other than the rise itself, from which this
5 Court can reasonably draw such an inference. And even if the Court could
6 reasonably infer that false or misleading marketing must have caused *some*
7 medically inappropriate prescriptions to be written, no evidence before the Court
8 enables it to conclude, without rank speculation, whether the number or volume of
9 such medically inappropriate prescriptions contributed to the alleged public
10 nuisance, and if so, to what extent. Plaintiffs have themselves (in argument and
11 through their expert witness Dr. David Herzberg) described the opioid crisis as
12 multifaceted, with contributing actors including manufacturers, distributors,
13 pharmacies, doctors, the illegal drug trade, the FDA, the DEA, and the State of
14 California. While Plaintiffs are not required to prove the exact contribution of each
15 of these contributing actors, including of each Defendant, they must nevertheless
16 prove that the contribution of each Defendant was more than “negligible or
17 theoretical.” *ConAgra* at 79, 102.

18 Here, with no evidence to identify the existence or volume of medically
19 inappropriate opioid prescriptions caused by Defendants’ allegedly improper
20 marketing, determining whether such cause was “negligible or theoretical”
21 (insufficient to establish causation), or minor (sufficient to establish causation) in
22 relation to the overall opioid crisis, would require wholly unsupported speculation.

23 Instead, Plaintiffs’ evidence undermines their own case. Plaintiffs’ evidence
24 shows that, as everybody knew, as the number, dose and duration of prescriptions
25 increase, so too do the adverse downstream consequences. But this does not assist
26 Plaintiffs’ case. The FDA knew about the risks of opioids; that is precisely why the
27 FDA designated opioids as Schedule II drugs. The FDA continues to approve these
28

1 drugs for use where medically appropriate. And when the FDA was requested in
2 2013, at a time when the opioid crisis was already full blown, to impose dose or
3 duration limits, the FDA declined to do so, leaving such decisions instead to the
4 healthcare practitioner in consultation with his or her patient.

5 And as already noted, the California Legislature has approved, and continues
6 to approve, the availability of opioid medications, through prescriptions, by passing
7 the laws described above.

8 As the Historical and Statutory Notes to Business & Professions Code section
9 2241.5 state, “it is the intent of the Legislature to encourage physicians to provide
10 adequate pain management to patients in California consistent with Section 2241.5.”
11 And the California Legislature made clear its intention to expand, rather than
12 restrict, the appropriate prescribing of opioid medications. In 1990 section 2241.5
13 provided for the prescribing or administering of controlled substances “for a
14 diagnosed condition *causing intractable pain*.” (Emphasis added.) That language was
15 repeated in a revised version of section 2241.5 in 2004. Effective January 1, 2007 the
16 section was amended to read as follows: “A physician and surgeon may prescribe for,
17 or dispense or administer to, a person under his or her treatment for a medical
18 condition dangerous drugs or prescription controlled substances for the treatment of
19 pain *for a condition causing pain, including, but not limited to, intractable pain*.”
20 (Emphasis added.) And subsection (b) was revised to read straightforwardly as
21 follows: “No physician and surgeon shall be subject to disciplinary action for
22 prescribing, dispensing, or administering dangerous drugs or prescription controlled
23 substances in accordance with this section.” (This replaced former subsection (c)
24 which had referenced intractable pain.)

25 As cited in *ConAgra*, ‘[o]f course, not every interference with collective social
26 interests constitutes a public nuisance. To qualify, and thus be enjoined [or
27 abatable], the interference must be both *substantial* and *unreasonable*.’ (Citation
28

1 omitted.) It is substantial if it causes significant harm and unreasonable if its social
2 utility is outweighed by the gravity of the harm inflicted. ([*Ibid.*].)” (*Santa Clara*
3 *I, supra*, 137 Cal.App.4th at p. 305, 40 Cal.Rptr.3d 313.)”

4 Regardless how the opioid crisis is defined, it is without question *substantial*.

5 But with no evidence to demonstrate or suggest that the increased
6 prescriptions were not medically appropriate, and with no evidence that even
7 attempts to quantify how medically inappropriate prescriptions caused or
8 contributed to the opioid crisis, Plaintiffs have failed to demonstrate that the
9 interference by Defendants, or any of them, was *unreasonable*. If every prescription
10 was medically appropriate for that patient, the highly regrettable but foreseeable
11 adverse downstream consequences are not unreasonable as that term is used in
12 *ConAgra* (and the cases it cites). Under Plaintiffs’ own theory and evidence, as
13 medically appropriate prescriptions continue to be written, adverse downstream
14 consequences will inevitably continue to occur, as the entirely foreseeable
15 consequence of the continued approval of opioids by both the Federal government
16 and the California Legislature.

17 Plaintiffs rely extensively on *ConAgra*, in support of their theories generally
18 and specifically in support of their arguments concerning aggregate proof as it
19 relates to causation. But *ConAgra* dealt with a product, lead paint, that had no
20 appropriate indoor use and therefore there was no reason for the court there to
21 distinguish between marketing and promotion resulting in proper versus improper
22 uses.

23 *State ex rel. Wilson v. Superior Court* (2004) 227 Cal.App.4th 579, also relied
24 upon by Plaintiffs, in fact shows the fallacy in their argument that aggregate proof
25 (at least in the form presented here) is somehow always sufficient. There, the Court
26 of Appeal reversed a trial court’s order granting summary adjudication, finding that
27 on the facts and issues presented there, the trial court had incorrectly concluded
28

1 that “proof of causation must be on a prescription-by-prescription and claim-by-claim
2 basis.” In holding that “causation may in many instances be inferred from evidence
3 that does not itself constitute direct evidence of reliance on an individual basis” the
4 Court of Appeal went on to hold that of course actual evidence would still be
5 necessary and theorized “In the underlying case, such evidence might, for example,
6 show that the individuals influencing or controlling the choice of drugs available for
7 prescription in a particular hospital or other formulary had specified a preference for
8 a BMS drug, to the exclusion of equally appropriate drugs of its competitors, only
9 after being provided substantial unearned benefits by BMS. The prescription of BMS
10 drugs under such a regimen might tend to show that the BMS prescriptions and
11 claims resulted more from the benefits provided than from individual treatment
12 decisions. (We do not suggest by this example that any such evidence exists or would
13 necessarily be persuasive or controlling.)” *Id.* at 608.

14 That is precisely the point here. Plaintiffs could have shown, or at least
15 attempted to show, that Defendants’ marketing and promotion caused health care
16 providers to write medically inappropriate prescriptions. Plaintiffs could have
17 shown, or at least attempted to show, singly or in the aggregate how many medically
18 inappropriate opioid prescriptions were written, and the correlation between those
19 numbers, and/or the increase in those numbers, and Defendants’ marketing efforts.
20 The Court will not opine on all the ways in which Plaintiffs could have sought to
21 discharge their burden, but Plaintiffs sought to introduce no such evidence.

22 Plaintiffs rely on *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3rd 51. That case
23 discusses in some detail inferences that can properly be drawn about the connection
24 between overpromotion and subsequent prescriptions. *Stevens* also, however,
25 stresses a very salient point. The Supreme Court there highlights the essential fact
26 that the overpromotion could be inferred to have caused the physician to prescribe
27 the drug “when not justified.” *Id.*, at 66, 68. Specifically, the Court held: “It is
28 reasonable to assume that the company’s efforts consciously or subconsciously

1 influenced [the physician]. In addition, plaintiff introduced expert testimony by a
2 physician that the advertising and promotion of the drug ‘played a role’ in inducing
3 physicians to prescribe it *when it was not sound practice to do so.*” Id at 68. (Italics
4 added.)

5 Here, Plaintiffs’ experts simply opined that Defendants knew, or must have
6 known, that as the gross number of prescriptions increased, and/or the dose and
7 duration of prescriptions increased, so did the risks of diversion and/or abuse. Again,
8 at the risk of repetition, in the context presented here the Court cannot conclude
9 that the increase in medically appropriate prescriptions can be a basis for public
10 nuisance liability, even if undesirable consequences follow.

11 12 3. Plaintiffs Have Failed to Prove Causation

13 In addition to its relevance to proof of the “unreasonableness” element of a
14 public nuisance claim as discussed above, the absence of evidence concerning
15 medically inappropriate prescriptions also breaks the chain of causation between
16 Defendants’ alleged wrongful conduct and the harms complained of. In *In re Firearm*
17 *Cases* (2005) 126 Cal.App.4th 959, the Court of Appeal stressed that causation is “a
18 necessary element of a public nuisance claim.” After citing to the Restatement
19 Second of Torts, the Court held as follows:

20 “This listing of examples of public nuisance illustrates the need for a
21 relationship between the conduct and the impending harm.”

22 “In this case, there is no causal connection between any conduct of the
23 defendants and any incident of illegal acquisition of firearms or criminal acts
24 or accidental injury by a firearm.”

25 *Id.* at 680.

26
27 Here, there is no evidence of medically inappropriate prescriptions caused or
28 induced by any allegedly false or misleading marketing and promotion by

1 Defendants, and the conclusion of the Court of Appeal is entirely apposite:

2 “Plaintiffs’ public nuisance claim fails for lack of any evidence of
3 causation. Their complaint attempts to reach too far back in the chain of
4 distribution when it targets the manufacturer of a legal, non-defective product
5 that lawfully distributes its product only to those buyers licensed by the
6 federal government.

7 We do not hold that the theories asserted would never be tenable under
8 different evidence. We merely find, based on the evidence presented here, that
9 the evidence does not sufficiently establish the alleged acts of the defendant
10 caused the diversion of firearms *to the criminal market.*”

11 *Id.* at 682-3. (Emphasis added.)

12
13 While the Court recognizes that Plaintiffs here contend that Defendants did
14 not “lawfully distribute” their products because they were using allegedly false or
15 misleading marketing and promotion, that does not change the essential fact that
16 there is no evidence supporting a causal connection between the alleged conduct and
17 adverse downstream consequences flowing from medically *inappropriate*
18 prescriptions. (“In this case, there is no causal connection between any conduct of
19 the defendants and any incident of illegal acquisition of firearms or criminal acts or
20 accidental injury by a firearm.” *In re Firearm Cases* 126 Cal.App.4th at 680.)

21 None of the arguably analogous public nuisance cases dictates a different
22 result.

23 In *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292,
24 the alleged public nuisance was the existence of lead paint in homes, buildings and
25 other property. In terms similar to some of those alleged here, the Court of Appeal
26 held as follows:

1 “Here, Santa Clara, S.F., and Oakland alleged that defendants assisted
2 in the creation of this nuisance by concealing the dangers of lead, mounting a
3 campaign against regulation of lead, and promoting lead paint for interior use
4 even though defendants had known for nearly a century that such a use of
5 lead paint was hazardous to human beings. Defendants ‘[e]ngag[ed] in a
6 massive campaign to promote the use of lead on the interiors and exteriors of
7 private residences and public and private buildings and for use on furniture
8 and toys.’ Had defendants not done so, lead paint would not have been
9 incorporated into the interiors of such a large number of buildings and would
10 not have created the enormous public health hazard that now exists. Santa
11 Clara, S.F., and Oakland have adequately alleged that defendants are liable
12 for the abatement of this public nuisance.”

13 Id. at 306.

14
15 If the similarities to the present case are obvious, so are the distinctions. The
16 FDA approves the use of opioids in appropriate circumstances, and the California
17 Legislature approves and promotes the use of opioids in appropriate circumstances.
18 The Court must accordingly draw a distinction between conduct resulting in the
19 anticipated, approved use, and conduct resulting in improper use. The evidence does
20 not permit the Court here to draw (and measure) that distinction.

21 *City of Modesto Redevelopment Agency v. Superior Court* (2004) 119
22 Cal.App.4th 28 involved, among other things, claims that the defendant instructed
23 users to dispose of certain hazardous chemicals into drains and sewers. The court
24 there had no occasion to determine appropriate versus inappropriate discharge. On
25 the facts alleged *any* discharge into drains and sewers was potentially problematic.
26 (The Court of appeal was addressing these issues in the context of demurrers and
27 motions for summary adjudication, not after trial.)

28 In *People ex rel. Gallo v. Acuna* (1997) 14 Cal.App.4th 1090, the California

1 Supreme Court, in upholding an order enjoining certain gang behavior, carefully
2 examined whether the enjoined behavior improperly included “constitutionally
3 protected associational interests.” The Court there found that in the area covered by
4 the injunction, the gangs “appeare[d] to have had no constitutionally protected or
5 even lawful goals . . . So far as the record before the trial court shows, the gangs and
6 their members engaged in no expressive or speech-related activities which were not
7 either criminally or civilly unlawful or inextricably intertwined with unlawful
8 conduct.” *Id.* at 1121. Here, it is indisputable that the opioid prescriptions included
9 entirely lawful medically appropriate prescriptions. And no evidence establishes the
10 existence, volume and/or number of medically inappropriate prescriptions.
11

12 Accordingly, on the basis of the evidence presented here, the Court finds that
13 Plaintiffs have failed to prove an actionable public nuisance for which Defendants, or
14 any of them, are legally liable.

15 Nothing stated herein is intended to suggest that false or misleading
16 marketing and promotion that results in medically inappropriate prescriptions being
17 written may not constitute an actionable public nuisance. But that is not the
18 evidence before this Court.

19 The Court declines to rule on the allegedly false or misleading statements in
20 any of the materials falling outside of the limitations periods applicable to the FAL
21 or UCL claims, as they are not relevant to the Court’s decision.
22

23 B. The False Advertising and Unfair Competition Law Claims

24 “California’s false advertising law (§ 17500 et seq.) makes it “unlawful
25 for any person, ... corporation ..., or any employee thereof with intent directly
26 or indirectly to dispose of real or personal property or to perform services ... or
27 to induce the public to enter into any obligation relating thereto, to make or
28

1 disseminate ... before the public in this state, ... in any newspaper or other
2 publication ... or in any other manner or means whatever ... any statement,
3 concerning that real or personal property or those services ... which is untrue
4 or misleading, and which is known, or which by the exercise of reasonable
5 care should be known, to be untrue or misleading....” (§ 17500.) Violation of
6 this provision is a misdemeanor. (*Ibid.*) As with the UCL, an action for
7 violation of the false advertising law may be brought either by a public
8 prosecutor or by “any person acting for the interests of itself, its members or
9 the general public,” and the remedies available to a successful private plaintiff
10 include restitution and injunctive relief. (§ 17535.)

11 This court has recognized that “[a]ny violation of the false advertising
12 law ... necessarily violates” the UCL. (*Committee on Children's Television,*
13 *Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 210, 197 Cal.Rptr. 783, 673
14 P.2d 660.) We have also recognized that these laws prohibit “not only
15 advertising which is false, but also advertising which [,] although true, is
16 either actually misleading or which has a capacity, likelihood or tendency to
17 deceive or confuse the public.” (*Leoni v. State Bar* (1985) 39 Cal.3d 609, 626,
18 217 Cal.Rptr. 423, 704 P.2d 183.) Thus, to state a claim under either the UCL
19 or the false advertising law, based on false advertising or promotional
20 practices, “it is necessary only to show that ‘members of the public are likely
21 to be deceived.’” (Citations omitted.)

22 *Kasky v. Nike, Inc.* (2002) 27 Cal.4th 939, 950–951, as modified (May 22,
23 2002)

24
25 An important issue arising from the statute, and the cases interpreting it, is
26 that the statements complained of must have been “ma[de] or disseminate[d] . . .
27 before the public,” here, in particular, health care providers and patients. Indeed,
28

1 Part 3 of the Business and Professions Code, which commences with section 17500,
2 is entitled “Representations to the Public.” Thus, an allegedly false or misleading
3 statement in an internal company document, that was in no way published or
4 disseminated before the public, would not qualify as “false advertising” under the
5 statute or applicable cases.

6 There is no dispute as to the applicable limitations periods for the FAL and
7 UCL claims. They are as follows.

8 FAL: From and after May 21, 2011 with respect to the Janssen Defendants,
9 the Allergan Defendants, and the Endo Defendants; From and after March 23, 2015
10 with respect to the Teva Defendants.

11 UCL: From and after May 21, 2010 with respect to the Janssen Defendants,
12 the Allergan Defendants, and the Endo Defendants; From and after March 23, 2014
13 with respect to the Teva Defendants.

14 Regarding internal documents that were used in the training of sales
15 representatives, but not themselves “published,” the Court draws the reasonable
16 inference that the sales representatives would have relied on such documents in
17 their doctor visits.

18 What is more problematic is to determine whether the Court can identify,
19 without simply speculating, precisely what statements in those documents were
20 repeated by sales representatives to anyone they called on. This problem has two
21 components.

22 First, there are documents where Plaintiffs do not rely on the actual words in
23 the document, but rather argue about what the words used must mean. Thus the
24 Court must attempt to determine what was said, before making a determination as
25 to whether what was said amounted to a false or misleading statement.

26 And second, there are documents where allegedly false statements appear
27 alongside much other information, and the Court must decide whether Plaintiffs
28 have proven that the false statements, and not the other information, were

1 communicated.

2 For all statements relied on, Plaintiffs must prove that they were likely to
3 deceive the recipient. *In re Tobacco II Cases*, 46 Cal. 4th 298, 312 (2009). And,
4 “[w]here the advertising or practice is targeted to a particular group or type of
5 consumers, either more sophisticated or less sophisticated than the ordinary
6 consumer, the question whether it is misleading to the public will be viewed from
7 the vantage point of members of the targeted group, not others to whom it is not
8 primarily directed.” *In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 129 (2009).
9 Plaintiffs must prove “that a significant portion of the . . . targeted consumers,
10 acting reasonably in the circumstances, could be misled.” *Ebner v. Fresh, Inc.*, 838
11 F.3d 958, 965 (9th Cir. 2016) (emphasis added) (quoting *Lavie v. Procter & Gamble*
12 *Co.*, 105 Cal.App.4th 496 (2003)). A “mere possibility” that marketing “might
13 conceivably be misunderstood” by “unreasonable” consumers cannot support an FAL
14 claim. *Id.*

15 Whether a statement is misleading must be considered “in the context of the
16 entire document.” *Freeman v. Time, Inc.*, 68 F.3d 285, 290 (9th Cir. 1995).

17 Further, courts have held that FAL liability arises only from “specific rather
18 than general assertions.” *Newcal Indus., Inc. v. Ikon Off. Sol.*, 513 F.3d 1038, 1053
19 (9th Cir. 2008); accord *Demetriades v. Yelp, Inc.*, 228 Cal. App. 4th 294, 311 (2014).
20 That is, “a general, subjective claim about a product is non-actionable puffery”
21 because it is “extremely unlikely to induce consumer reliance.” *Newcal Indus.*, 513
22 F.3d at 1053.

23 Finally, advertising that takes a legitimate position on matters of scientific
24 debate cannot be false and misleading, as “[t]he UCL, FAL, and CLRA do not
25 requir[e] unanimous scientific consensus for each advertising claim on Defendants’
26 products.” *Reed v. NBTY, Inc.*, 2014 WL 12284044, at *14 (C.D. Cal. Nov. 18, 2014)
27 (applying California law).
28

1 Applying these principles, the Court's findings concerning the false or
2 misleading statements relied upon by Plaintiffs are as stated below. Given the
3 repetitive nature of the Court's findings, the Court does not attempt to explain its
4 findings at length for each document.

5
6 1. Janssen Defendants

7 The Janssen Appendix identifies 17 documents as containing false or
8 misleading statements. Of those, only 7 are shown to have been used in any manner
9 during the applicable limitations periods for the FAL (May 21, 2011) and UCL (May
10 21, 2010) claims. The undated document Risk Management (REMS) for Tapentadol
11 ER (P-CA-000658) is included in the 7, because the footnotes identify data from
12 2011, thus giving the document a date of 2011 or later. In Ex. JAN-CA-601315, only
13 pages .00015, .00016 and .00017 fall within the limitations periods. For all other
14 documents, nothing in the documents, or in any testimony concerning them,
15 establishes that they were used or referenced in any way during the limitations
16 periods.

17 The Court addresses the documents in the sequence in which they are cited in
18 the Janssen Appendix.

19 Sales Training for Nucynta and Nucynta ER (P-CA- 001787)

20 Plaintiff identifies as false or misleading a statement on page .020 of this
21 thirty-one page document. The Court finds nothing false or misleading in the
22 reference to "moderate to severe chronic pain." At p. .005, the document states that
23 "Nucynta ER is indicated for the management of moderate to severe chronic pain in
24 adults when a continuous, around-the-clock opioid analgesic is needed for an
25 extended period of time." That was the FDA approved use. As will be repeated often
26 herein in relation to many of the documents relied on by Plaintiffs, it is not a valid
27 criticism that every single page of a document does not contain all of the information
28 set forth in all of the other pages of the document. Any document must be viewed as

1 a whole, to determine whether in the context of the entire document, some part
2 thereof is false or misleading in a material way. The complained of statement is not
3 in context false or misleading, and there is no evidence to show, nor to support a
4 reasonable inference, that a sales representative, based on this document, falsely or
5 misleadingly misrepresented the appropriate use of the medication.

6 Risk Management (REMS) for Tapentadol ER (P-CA-000658)

7 Plaintiff identifies as false or misleading statements on page .0018 of this
8 thirty-nine page document. Plaintiffs' characterization of the statements is
9 inconsistent with the statements themselves, and again ignores context. Much of the
10 document is devoted to explicit explanations of the risks of opioids. The document
11 notes that the REMS programs are designed to mitigate serious risks associated
12 with particular drugs. The document discusses misuse, abuse, and diversion, shows
13 the rate of unintentional drug overdose deaths in the United States, and
14 distinguishes addiction from dependence. In the context of patients who become
15 physically dependent, but not addicted, the statement is made "once opioid
16 treatment is no longer needed, patients are able to discontinue opioid use without
17 difficulty, provided the dosage is tapered gradually." Based on the evidence
18 presented, the Court does not find this statement false or misleading. To the extent
19 that not all doctors appear to agree as to the ease or difficulty of tapering in a
20 physically dependent, but not addicted, patient, this professional disagreement does
21 not render the statements actionably false or misleading. The Court also does not
22 find the reference to risk assessment tools and procedures false or misleading. The
23 evidence presented confirmed the value of such tools and procedures in opioid
24 prescribing.

25 Nucynta ER Frequently Asked Questions (P-CA-000579)

26 Plaintiffs identify 6 allegedly false or misleading statements in this twenty-six
27 page document. Read in the context of the entire document, the Court finds none of
28 the identified statements to be false or misleading. In the scripted questions and

1 answers, the information includes that “Nucynta ER was not designed to produce
2 rapid onset for the treatment of acute pain, rather it is designed to manage chronic
3 pain over an extended period of time” (.0003), the health care provider is to be given
4 the “full Prescribing Information” (.0005), in determining dosage the health care
5 provider is advised that “close observation and titration are indicated until a
6 satisfactory dose is obtained on the new therapy” (.0007) and that “Treatment
7 should be individualized for the patient and clinical judgment should be used to
8 guide dosing and titration.” (.0007) The information includes that “Nucynta ER is
9 indicated for the management of moderate to severe chronic pain in adults when a
10 continuous, around-the-clock opioid analgesic is needed for an extended period of
11 time.” (.0013) This is the FDA approved use for the product. Consistent with FDA
12 guidance, the document notes that the Nucynta ER formulation was “designed to not
13 be amenable to splitting, crushing or dissolution.” (.0016) It does not claim that it is
14 effective in achieving this result, and indeed states “Like all long-acting opioids,
15 there is no post marketing experience with Nucynta ER tablets to assess whether
16 the formulation deters abuse, misuse, or diversion.” (.0016) Further, “Keep in mind,
17 Nucynta ER is a Schedule II controlled substance and can be abused in a manner
18 similar to other opioid agonists.” (.0017) In the context of the entire document, and
19 based on the evidence at trial, none of the challenged statements are simply untrue,
20 and none are false or misleading in the context presented.

21 Nucynta ER Launch Readiness (P-CA-000578)

22 Plaintiffs identify 10 allegedly false or misleading statements in this forty-
23 seven page document. Read in the context of the entire document, the Court finds
24 none of the identified statements to be false or misleading.

25 Plaintiffs identify as false or misleading any statement that can be
26 interpreted as saying that a particular opioid product improves function. While the
27 Court recognizes that the FDA has on occasion announced a concern that claims
28 about improved function should not be made absent scientific evidence, the Court is

1 persuaded based on the evidence in this trial that effective pain management and
2 improved, or improvements in, function are closely linked concepts. It seems beyond
3 debate that for a patient whose pain has been sufficiently controlled that they are
4 able to resume some of the basic functions of life -shopping, cooking, cleaning, and so
5 on - that patient's function has improved. Accordingly, where the statements
6 complained of cannot reasonably be interpreted as suggesting more than this basic
7 definition of improved function, they are not false or misleading.

8 At .0005, the document describes that Nucynta ER is "for the management of
9 moderate to severe chronic pain in patients 18 years of age or older when a
10 continuous, around-the-clock opioid analgesic is needed for an extended period of
11 time." At .0031, the document provides that the Nucynta ER REMS program will be
12 "[mailed] to HCPs 3 weeks prior to product availability in retail pharmacy" and that
13 the goals are "to inform patients and healthcare professionals about the potential for
14 abuse, misuse and addiction to Nucynta ER" and concerning the "safe use of
15 Nucynta ER."

16 More fundamentally, no evidence establishes or suggests that this document
17 was used to train sales associates or that the contents of this document were in any
18 other way communicated to persons outside the company.

19 A recurring issue with almost all the documents identified by Plaintiffs as
20 containing false or misleading messages is the extent to which the Court is being
21 asked to infer what parts of the documents were presented to health care
22 professionals, and in what manner. The only testimony on this subject was through
23 deposition extracts from sales representatives, introduced by Defendants, all of
24 whom testified that that they had scrupulously stayed within product labels in what
25 they presented. Plaintiffs persuasively argue that all of the training materials must
26 have played a role in what the sales representatives ultimately conveyed to the
27 healthcare providers. However, that argument does not account for internal non-
28 training materials. And, for training materials, given the mix of medically

1 appropriate information with the allegedly inappropriate information, and the
2 significant absence of evidence about how any of the information was actually
3 conveyed, inference necessarily becomes speculation as to what was actually
4 conveyed.

5 Duragesic Journal Advertising Overview, March 1991-Present (JAN-CA-
6 601318)

7 Plaintiffs identify 5 allegedly false or misleading statements in the 3
8 documents in this exhibit which fall within the limitations period (.00015, .00016
9 and .00017). In the context of opioid medications, these documents can certainly be
10 characterized as overoptimistic in their visual and verbal presentation. It is a closer
11 call whether they can properly be characterized as false and/or misleading. The
12 Journal advertisements appear aimed at patients, although they would also be
13 available to healthcare providers. On balance, because as directed to patients, these
14 advertisements could only have prompted patients to seek opioids from their doctor
15 (as opposed to directly buying them themselves), and as directed to healthcare
16 providers, the context would have been readily understood, the Court finds none of
17 the identified statements to be false or misleading. In reaching this conclusion, the
18 Court also takes account of the testimony by Plaintiffs' expert witness, Doctor
19 Matthew Perri, that in his review of Janssen's marketing materials, he "found that
20 the claims in Janssen's marketing materials track the FDA-approved labels fairly
21 consistently" (Tr. 2245: 2-6) and he "did not see any indication of Janssen failing to
22 include important safety information in its marketing pieces." Tr. 2252: 16-20.

23 Nucynta/Nucynta ER Speakers' Slide Decks titled "New Perspectives in the
24 Management of Moderate to Severe Chronic Pain" (P-CA-01793)

25 Plaintiffs identify 4 allegedly false or misleading statements in this sixty-one
26 page document. Read in the context of the entire document, the Court finds none of
27 the identified statements to be false or misleading. As with earlier documents, it is
28 not a valid criticism that all information from the entire document must be

1 contained on every page. Every statement must be read in context. While page .003
2 has the heading “New Perspectives in the Management of Moderate to Severe
3 Chronic Pain,” page .005 sets forth the full indication for Nucynta, on the one hand,
4 and Nucynta ER, on the other. On the page bearing the heading “Nucynta ER: Low
5 Incidence of Opioid Withdrawal Symptoms”(033), data is cited from clinical studies,
6 with the summary “There were 635 subjects in the Nucynta ER group assessed
7 between Day 2 and Day 4 after abrupt cessation of treatment with 12% and 2% of
8 subjects having mild or moderate withdrawal, respectively” and the further
9 statement “Withdrawal symptoms may be reduced by tapering Nucynta ER.” (.033)
10 That same page noted, in bold print, “Please see full Prescribing Information,
11 including Boxed WARNING, available at this event.” Page .038 commenced with
12 “Risk Evaluation and Mitigation Strategy (REMS)” that was followed by 10 pages of
13 “Important Safety Information.”

14 Keith Candiotti, MD “Use of Opioid Analgesics in Pain Management” (JAN-
15 CA-600078)

16 Plaintiffs identify 5 allegedly false or misleading statements in this article.
17 The article sets forth the author’s opinions, supported, where applicable, by citations
18 to various studies, including studies relied upon by the various expert witnesses in
19 this case. Read in the context of the entire document, the Court finds none of the
20 identified statements to be false or misleading. Plaintiffs’ expert witness on
21 marketing, Doctor Matthew Perri, identified this document as one showing
22 Janssen’s promotion of its products, but otherwise offered no opinions concerning the
23 contents. No other witness testified to the content of this document. None of the
24 criticisms of this document, which essentially asked the Court to determine whether
25 the document provides sound medical advice, identify statements which can be
26 characterized as false or misleading for FAL or UCL purposes.

1 2. Allergan Defendants

2 The Allergan Appendix identifies 21 documents as containing false or
3 misleading statements. Of those, 14 are dated within the applicable limitations
4 periods for the FAL (May 21, 2011) and UCL (May 21, 2010) claims. For all other
5 documents, nothing in the documents, or in any testimony concerning them,
6 establishes that they were used or referenced in any way during the limitations
7 periods.

8 The Court addresses the documents in the sequence in which they are cited in
9 the Allergan Appendix.

10 Kadian Learning System (P-CA-000251.003 - .194)

11 Although the Appendix identifies three versions of the Kadian Learning
12 System, the Court addresses only the 2010 version (and thus rows 1, 3, 5 through 11,
13 13, and 15 through 18), as no evidence establishes that the earlier versions were
14 used or relied upon during the relevant limitations periods. Where Plaintiffs
15 reference an earlier version, and the same or substantially similar language appears
16 in the 2010 version, it is included in the rows identified.

17 As with some of the documents discussed earlier, this 192-page document
18 requires a double inference. The first inference, which the Court reasonably draws
19 based upon the intended purpose of this document, is as follows: The information in
20 this document was provided to salespeople so that they could communicate
21 information to the healthcare providers on whom they called, and information from
22 this document was in fact communicated to healthcare providers. The second, more
23 problematic, inference involves determining whether what was actually conveyed by
24 the salespeople contained false or misleading information. Because the Court
25 concludes that none of the statements complained of contained a blatant falsehood or
26 inaccuracy, the Court further concludes that it cannot reasonably draw the inference
27 that information from this document was necessary communicated to healthcare
28 providers in a false or misleading manner.

1 The 192-page document comprises nine chapters, including Chapter 5 on
2 “Drug Abuse and Chronic Pain,” and in Chapter 6 a section on “Addiction
3 Dependence, and Tolerance.” Chapter 9 is entitled “Safety and Adverse
4 Experiences.” The black box FDA approved labeling for Kadian is set forth under the
5 heading “FDA Safety Warnings for Kadian” (at pages .166 -169). Reviewing the
6 document as a whole, the Court agrees with the assessment of Dr. Warfield that the
7 document does not improperly minimize risks. Regarding specific statements
8 alleged, the Court finds none of them to be false or misleading in the context of the
9 document as a whole. Where Plaintiffs challenge not the words used, but their
10 meaning or import, the Court cannot speculate as to how that might have been
11 conveyed to a healthcare provider.

12 Regarding “function,” the Court has addressed that issue above.

13 Regarding “pseudoaddiction,” this is a medically recognized term, describing a
14 condition where a patient seeking more or stronger opioid medication might be doing
15 so because their pain is undertreated, and not because they have or are developing
16 an abuse disorder. The California Legislature itself recognized this condition,
17 without using the term “pseudoaddiction,” in Health and Safety Code section
18 11156(b)(2): “[A] person whose drug-seeking behavior is primarily due to the
19 inadequate control of pain is not an addict within the meaning of this section.”

20 Regarding “no ceiling dose,” this is a medically accurate statement and
21 nothing in the document states or suggests that a healthcare provider should
22 interpret “no ceiling dose” to mean that they can increase the dosage indefinitely.
23 Instead, the Learning System states: “Doses are titrated to pain relief, and so no
24 ceiling can be given as to the recommended maximal dose especially in patients with
25 chronic pain of malignancy. In such cases, the total dose of Kadian should be
26 advanced until the desired therapeutic endpoint is reached or clinically significant
27 opioid-related adverse reactions occur.” (.164). The section is immediately followed
28 by “Information for Patients” and the Black Box FDA warnings.

1 Regarding “addiction is rare”: The document does not state that addiction is
2 rare. Rather, Plaintiffs identify various statements which they contend are intended
3 to convey that addiction is rare. First, the Court is left to speculate as to precisely
4 what information was actually imparted to healthcare providers. Without any
5 evidence on that issue, the Court cannot determine whether such information was
6 false or misleading. Second, to the extent that the document states that addiction is
7 not commonplace, it is accurate, based on the testimony in this trial. Plaintiffs
8 identify the following allegedly false or misleading statement: “Clinicians who had
9 been incorrectly trained to believe that taking opioids for a prolonged period would
10 always result in addiction were surprised that most of these patients never exhibited
11 any signs or symptoms of addictive disease.” (.085) That statement appears in a
12 section on “Substance Abuse and Chronic Pain” which provides a summary opioid
13 use chronology, and concludes by stating: “The responsibility for knowing state and
14 federal regulations regarding prescribing, dispensing, or administering controlled
15 substances ultimately lies with the clinician. However, the Federation of State
16 Medical Boards specifically states that clinicians should not fear disciplinary action
17 for ordering, prescribing, or administering controlled substances for a legitimate
18 medical purpose in the course of professional practice. Prescribing and
19 administering controlled substances for pain are legitimate if prescribed for a
20 medical purpose. Prescribing should be done in the context of a diagnosis and
21 documentation of unrelieved pain as part of a physician-patient relationship.
22 (Federation of State Medical Boards 2004).” (.086). Dr. Lembke testified that one in
23 four patients prescribed opioids would become addicted. As Defendants point out,
24 the studies relied upon by Dr. Lembke for that conclusion are inadequate to support
25 it. The more reliable data would suggest less than 5%, rather than 25%. Under
26 either number, addiction based solely on the patient having been prescribed opioids
27 does not occur in “most of these patients.”

28 Most fundamentally, the Court has no evidence of statements actually made

1 to healthcare providers, or anyone else, based on this document. Given the very
2 significant amount of information contained in the document, the Court cannot
3 speculate as to what a salesperson chose to convey, or in precisely what manner.
4 Absent such evidence, the Court cannot make a determination whether false or
5 misleading information was actually published, as required for FAL or UCL liability.

6 Putting it All Together- 2011 Kadian National Sales Meeting Slideshow by
7 Jennifer Altier (P-CA-000265)

8 The challenged statement does not “claim there is no dose of opioids too high
9 for the treatment of chronic non-cancer pain” and does not “state there is no ceiling
10 dose for opioids without noting that the risks of addiction, overdose, and death
11 increase with dosage.” It is accurate that there is no maximum dose for Kadian, as
12 demonstrated by the Kadian label. The February 2009 FDA-approved Kadian label,
13 for example, stated that “No guidance can be given as to the recommended maximal
14 dose, especially in patients with chronic pain of malignancy. In such cases the total
15 dose of KADIAN® should be advanced until the desired therapeutic endpoint is
16 reached or clinically significant opioid-related adverse reactions intervene.” (AL-CA-
17 300275.00021.) Further, the referenced statements are in an email with an 85-page
18 attachment, which includes the following information: “There is growing public
19 safety concern regarding the use of long-acting opioid products . . . Concern over the
20 increase in adverse events associated with LAOs, including improper dosing,
21 indication and patient selection, as well as abuse and addiction, has led the FDA to
22 request sponsors of certain opioids to develop a Risk Evaluation and Mitigation
23 Strategy or ‘REMS.’ . . . The goal of REMS programs is to ensure that the benefits of
24 the drugs continue to outweigh the risks associated with use of LAO” (.009).

25 July 2011 Sales Training Class - Introduction of Oxymorphone Hydrochloride
26 Extended-Release Tablets, CII (P-CA-001813)

27 Nothing in the challenged statement is shown to be inaccurate (it is
28 essentially a statement about product availability and dosage strength for a generic)

1 and the document discusses indications and usage, and contains the boxed warnings
2 for the product.

3 Kadian Prescriber Research (P-CA-001645)

4 As the document makes clear, it is a “summary report from prescriber
5 research” based on telephone interviews with prescribers. (See p. .001 read with
6 .003.) The challenged statements do not represent statements attributable to any
7 Allergan Defendant (or any other defendant in this case).

8 Kadian Marketing Overview- Sales Representative Training (AL-CA-300050);
9 Objection Handling Messaging (July 13, 2011) and Kadian Promotional Training
10 Slides (October 2011) (P-CA-000128); 2011 Kadian Training Meeting - Managed
11 Markets (P-CA-000079); Regional Meetings November 2011 Generic Kadian Sales
12 Team Meeting (P-CA-000013); Email from Jennifer Altier attaching the approved
13 generic Kadian telescript (P-CA-000065); Kadian Marketing Overview- Sales
14 Representation Training (P-CA-000127); Kadian New Strengths Launch (P-CA-
15 000045)

16 The Court finds nothing false or misleading in the statements cited from these
17 documents.

18 Kadian Comparison Detailer (AL-CA-300114); Behind the Scenes: The Kadian
19 Capsules Story – Promotional Piece (P-CA-001708); “When you can prescribe the
20 benefits of Kadian capsules” detail piece (P-CA-001707); Kadian Co-Pay Assistance
21 Program Brochure (AL-CA-300075); Kadian Sales Aid (P-CA-001706); Kadian
22 Reprint, “Effect of Concomitant of Ingestion of Alcohol on the In Vivo
23 Pharmacokinetics of Kadian” from the Journal of Pain (P-CA-001725); Kadian
24 Conversion Guide Sales Aid (P-CA-001727)

25 As Plaintiffs note, these documents were distributed until February 2010.
26 They accordingly falls outside the applicable limitations periods.

27 Kadian Dosing strengths brochure (P-CA-001718); Kadian Dosing Guide (P-
28 CA-001709); Generic is Now Available - Oxymorphone Hydrochloride Extended-

1 Release Tablets (P-CA-000070)

2 The Court finds nothing false or misleading in the statements cited from these
3 documents.

4

5 3. Endo Defendants

6 The Endo Appendix identifies 11 documents as containing false or misleading
7 statements. Of those, 4 are dated within the applicable limitations periods for the
8 FAL (May 21, 2011) and UCL (May 21, 2010) claims. One is dated earlier, but the
9 Endo Defendants concede its use during the limitations period. For all other
10 documents, nothing in the documents, or in any testimony concerning them,
11 establishes that they were used or referenced in any way during the limitations
12 periods.

13 The Court addresses the documents in the sequence in which they are cited in
14 the Endo Appendix.

15 Opana ER Opioid Analgesics Overview: Product Therapeutic and Learning
16 System (P-CA-000417)

17 The Court finds nothing false or misleading in this 62-page document, as a
18 whole or in the statements cited from this document. In the Introduction the
19 document states “However, the remarkable utility of opioids for pain relief and their
20 unquestionable benefits in alleviating patient suffering are counter-balanced by the
21 serious consequences of their misuse and abuse. As a Sales Representative working
22 in the field of pain management, it is important for you to be aware of both these
23 perspectives when working with this drug class and speaking with healthcare
24 providers. Risk management with opioids will be discussed at length in the next
25 module.”

26 Opana ER Detail Aid (P-CA-000406)

27 The Court finds nothing false or misleading in this document. Plaintiffs do not
28 challenge particular words or statements as false or misleading, instead arguing for

1 a misleading interpretation. That the product was “designed to be crush resistant” is
2 consistent with the FDA’s directions for the marketing of the product.

3 Letter from Endo to Julie Suko, decisionmaker for “medication division
4 support organization,” regarding Reformulated Opana ER (P-CA-000507)

5 There is no evidence identifying the addressee of this letter, no evidence that
6 the letter was actually sent, and no evidence that the letter was sent to or received
7 by any person in California. It is accordingly not relevant to either the FAL claim or
8 the UCL claim.

9 What you should know about treating your pain with opioids (P-CA-00416)
10 (Incorrectly cited as DEF-CA-101950)

11 The Court finds nothing false or misleading in the statement cited from this
12 document.

13 Responsible Opioid Prescribing, a Physician’s Guide, by Dr. Scott M. Fishman
14 (DEF-CA-101950)

15 Despite its date, the evidence shows, and the Court finds, that this document
16 was used in California during the limitations periods. The Court also finds that the
17 Endo Defendants directly supported the preparation and publication of this
18 document. Specifically, Ex. P-CA-000441 discusses “Endo’s commitment on
19 promoting education . . . “ and that this commitment included “support[ing] the
20 development of a handbook,” specifically the document now in question.

21 This 74-page handbook is, as the title suggests, directed to healthcare
22 practitioners. Reading all of the complained of statements in context, the Court finds
23 none of them to be false or misleading.

24 In the Foreword Dr. James N. Thompson, President and CEO, Federation of
25 State Medical Boards states: “Patients in pain who rely on opioids for analgesia and
26 improved function deserve access to safe and effective medication; to deprive them of
27 optimal pain-relief certainly does them harm. Yet these same life-restoring
28 medications carry the potential to do grave harm to patients who may be at risk for

1 addiction and abuse.” (.000005) There are numerous other citations in the handbook
2 to the critical need to balance pain relief on the one hand with the attendant risks of
3 the medication. The handbook notes that “Application of this information in any
4 situation remains the professional responsibility of the practitioner.” (.000003)
5 Stated most simply, none of the complained of statements in this handbook, written
6 by a doctor for use by doctors, are demonstrably factually inaccurate or can
7 reasonably be characterized as false or misleading for purposes of FAL or UCL
8 liability.

9 10 4. Teva USA

11 The Teva USA Appendix identifies 11 documents as containing false or
12 misleading statements.

13 The Court addresses the documents in the sequence in which they are cited in
14 the Teva USA Appendix.

15 Imagine the Possibilities, Fentora Fall Manager’s Meeting presentation (P-
16 CA-001758)

17 No evidence explains how any part of this document was used or published
18 outside the company so as to constitute a false or misleading statement likely to
19 deceive the recipient.

20 2014 Vantrela ER Launch Plan (CEX 003)

21 No evidence explains how any part of this document was used or published
22 outside the company so as to constitute a false or misleading statement made or
23 disseminated to the public and likely to deceive the recipient.

24 Fentora Sales Call Log (P-CA-001352)

25 Nothing in the document purports to contain or constitute a false or
26 misleading statement.

27 Fentora Sales Call Log (P-CA-001396)

28 Nothing in the document purports to contain or constitute a false or

1 misleading statement.

2 Fentora Targeting Report (P-CA-001511.002 - .024)

3 Nothing in the document purports to contain or constitute a false or
4 misleading statement.

5 2006-2015 speaker program data (P-CA-001346)

6 Nothing in the document purports to contain or constitute a false or
7 misleading statement made or disseminated to the public.

8 2019 Pain Matters Website (P-CA-00816)

9 At the risk of repetition, the Court notes that the statements in this
10 document/website must be viewed in the context of all other statements/information
11 contained therein. The Court finds nothing false or misleading in the statements
12 cited from this document/website.

13 Discovery Channel Pain Matters Flyer (P-CA-001532)

14 The Court finds nothing false or misleading in the statement cited from this
15 document.

16 2004-2018 Payments to Pain Organizations (P-CA-001459)

17 Nothing in the document purports to contain or constitute a false or
18 misleading statement.

19 2012 to 2014 Grant requests (P-CA-001332)

20 Nothing in the document purports to contain or constitute a false or
21 misleading statement made or disseminated to the public.

22
23 **5. Cephalon Inc.**

24 The Cephalon Appendix identifies 26 documents as containing false or
25 misleading statements. Of those, only 2 are dated within the applicable limitations
26 periods for the FAL (May 21, 2015) and UCL (May 21, 2014) claims. One (DEF-CA-
27 101950) is dated earlier, but as noted earlier, there is evidence of its use during the
28 limitations period. For the other documents, nothing in the documents, or in any

1 testimony concerning them, establishes that they were used or referenced in any
2 way during the limitations periods. To the extent that the Court could indulge the
3 speculation that information from earlier documents may have found its way into
4 later presentations, it would require still further speculation to determine precisely
5 what may have been disseminated to the public.

6 The Court addresses the three documents in the sequence in which they are
7 cited in the Cephalon Appendix.

8 Fentora Sales Call Log (P-CA-001352)

9 Nothing in the document purports to contain or constitute a false or
10 misleading statement.

11 Fentora Sales Call Log (P-CA-001396)

12 Nothing in the document purports to contain or constitute a false or
13 misleading statement.

14 Responsible Opioid Prescribing, a Physician's Guide, by Dr. Scott M. Fishman
15 (DEF-CA-101950)

16 As already noted above, reading all of the complained of statements in
17 context, the Court finds none of them to be false or misleading.

18
19 V. Conclusion

20
21 The Court finds that Plaintiffs have failed to prove an actionable public
22 nuisance for which Defendants, or any of them, are legally liable.

23 As the Court finds none of the identified statements, within the applicable
24 limitations periods, to be false or misleading, Plaintiffs' claims fail under both the
25 FAL and UCL.

26 There will accordingly be judgment for Defendants on all claims.

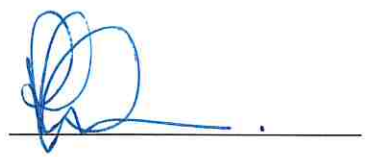
27 Defendants are hereby Ordered to file and serve a Proposed Statement of
28 Decision consistent herewith, and a proposed Judgment, within 30 days of service

1 hereof.

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The Clerk is ordered to give notice.

Dated: 11/1/2021



Hon. Peter J. Wilson