

# Post-Acquisition Kadian Timeline (2009-2020)



# Norco Timeline

1970s

Combo hydrocodone/  
acetaminophen products approved

1997

Norco approved as  
“branded generic”

2003

Marketing ends

Dec. 31, 2020

Voluntarily  
Discontinued

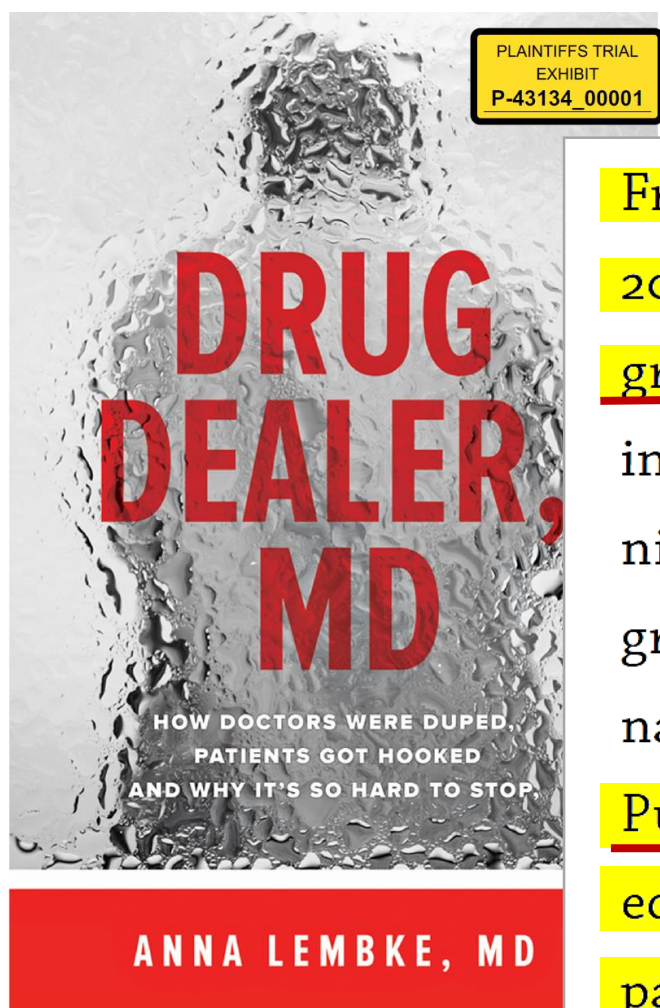
LIMITED MARKETING

NO MARKETING

STOP



'70 '71 '72 '95 '96 '97 '98 '99 '00 '01 '02 '03 '04 '05 '06 '07 '08 '09 '10 '11 '12 '13 '14 '15 '16 '17 '18 '19 '20



From 1996, when OxyContin was introduced to the market, to July 2002, Purdue has funded over 20,000 pain-related educational programs through direct sponsorship or financial grants. These grants included support for programs to provide physicians with opportunities to earn required continuing medical education credits, such as grand round presentations at hospitals and medical education seminars at state and local medical conferences. During 2001 and 2002, Purdue funded a series of nine programs throughout the country to educate hospital physicians and staff on how to comply with JCAHO's pain standards for hospitals and to discuss postoperative pain treatment. Purdue was one of only two drug companies that provided fund-

Key Opinion  
Leaders

Continuing  
Medical  
Education

Seeding the  
Medical  
Literature

Clinical Decision  
Support Tools

Front Groups

FSMB

California  
Opioid-Related  
Legislation

Joint Commission

# Continuing Medical Education

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19 Attorney Da  
20 [Additional  
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Word Count: 15,541

84. Defendants employed CME as part of the strategy to spread their message about opioids starting in the late 1990s and continuing to today, as an important element of the tactics to increase prescribing. Illustrative of the significance of the CME strategy, Endo budgeted nearly half of its 2009 \$15.8 million Opana brand promotional budget for Promotional Speaker Programs and reported its programs had a nearly 200% ROI. **P-24561.**

THE CITY  
FRANCISCO  
PEOPLE C  
Acting by  
Attorney D

v.

PURDUE L

Defendants.

DECLARATION OF ANNA LEMBKE, M.D.  
3:18-cv-07591-CRB

# Seeding The Medical Literature

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20 THE CITY  
21 FRANCISCO  
22 PEOPLE C  
23 Acting by  
24 Attorney D

25 v.

26 PURDUE L

85. **Seeding the Medical Literature:** Opioid manufacturers seeded the very foundation of evidence-based medicine, the peer-reviewed medical literature, by promoting studies that supported use of opioids for chronic pain based on misleading evidence. A common practice was the use of studies showing *short term* benefit of opioids (12 weeks or less) in patients with chronic pain (pain every day for 3 months or more); which is different than studies showing *long-term* benefit of opioids in patients with chronic pain, a subtle but crucial distinction.:

DECLARATION OF ANNA LEMBKE, M.D.  
3:18-cv-07591-CRB



# Clinical Decision Support Tools

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17 of California, acting by and through San Francisco  
18 Attorney David Chiu

19 [Additional counsel appear on signature page.]

20 UNITED STATES  
21 NORTHERN DISTRICT  
22 OF  
23 SAN FRANCISCO

24 THE CITY AND COUNTY OF SAN  
25 FRANCISCO, CALIFORNIA and THE  
26 PEOPLE OF THE STATE OF CALIFORNIA  
27 Acting by and through San Francisco City  
28 Attorney DAVID CHIU,

Plaintiff,

v.

24 PURDUE PHARMA L.P., et al.  
25 Defendants.

88. An example of clinical decision support tools include items like the “Pain Evaluator” pictured below, described by one opioid manufacturer as a “Pain Assessment tool which will help the HCP [health care provider] understand the patients [sic] pain, not limited to a number on the scale but a clearly [sic] understanding of what they can do because of pain.” P-24561. The Pain Evaluator consists of a series of happy to sad faces, with the happiest face representing “no hurt” and the saddest face representing “hurts worst.” Beyond its grammatical flaws, the Pain Evaluator has never been shown to improve pain outcomes and does not add to understanding patients’ pain. Rather, such tools have been shown to increase opioid prescribing, as described in my book, *Drug Dealer, MD*.

# Professional Medical Societies And Patient Advocacy Groups

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25 Defendants.

89. **Professional Medical Societies and Patient Advocacy Groups:** An investigative report by the US Senate Finance Committee identified about \$65 million given by opioid manufacturers to professional groups such as the American Pain Society, the American Academy of Pain Medicine, and the Joint Commission Resources, to promote pain treatment practice guidelines that advocated unwarranted, expanded use of opioids. So-called “patient advocacy” groups were also funded by the opioid manufacturers. The Committee Report found that the amounts contributed suggest that “manufacturers view these organizations as helpful extensions of their sales and marketing efforts.” Significant funds were contributed by Teva (which led the way), along with Purdue, Janssen, Endo and Mallinckrodt. P-18565\_00002, 9.



# Federation Of State Medical Boards

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Word Count: 15,541

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19 [Additional

94. Between 2007 and 2012, the FSMB received approximately \$1.3 million in funding from Purdue, Johnson & Johnson and Endo.

20 THE CITY AND COUNTY OF SAN  
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22 PEOPLE OF THE STATE OF CALIFORNIA,  
23 Acting by and through San Francisco City  
24 Attorney DAVID CHIU,

25 Plaintiff,

26 v.

27 PURDUE PHARMA L.P., et al.

28 Defendants.

Case No. 3:18-cv-07591-CRB

Declaration of Anna Lembke, M.D.

Judge: Honorable Charles R. Breyer

DECLARATION OF ANNA LEMBKE, M.D.  
3:18-cv-07591-CRB

# Joint Commission (JCAHO)

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Word Count: 15,541

101. Between 1999 and 2002, the JCAHO received funding from Purdue to develop and disseminate new pain management standards. In 2012, a letter from the JCAHO responding to a request from the US Senate Finance Committee stated that support for its “pain management activities” was provided by Purdue, Endo Pharmaceuticals, Ortho-McNeill, The National Pharmaceutical Council, Pfizer, and Abbott Labs, and that it had received almost \$4 million from organizations that made or promoted the use of opioid-based drugs.

DECLARATION OF ANNA LEMBKE, M.D.  
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~~Key Opinion  
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~~Seeding the  
Medical  
Literature~~

~~Clinical Decision  
Support Tools~~

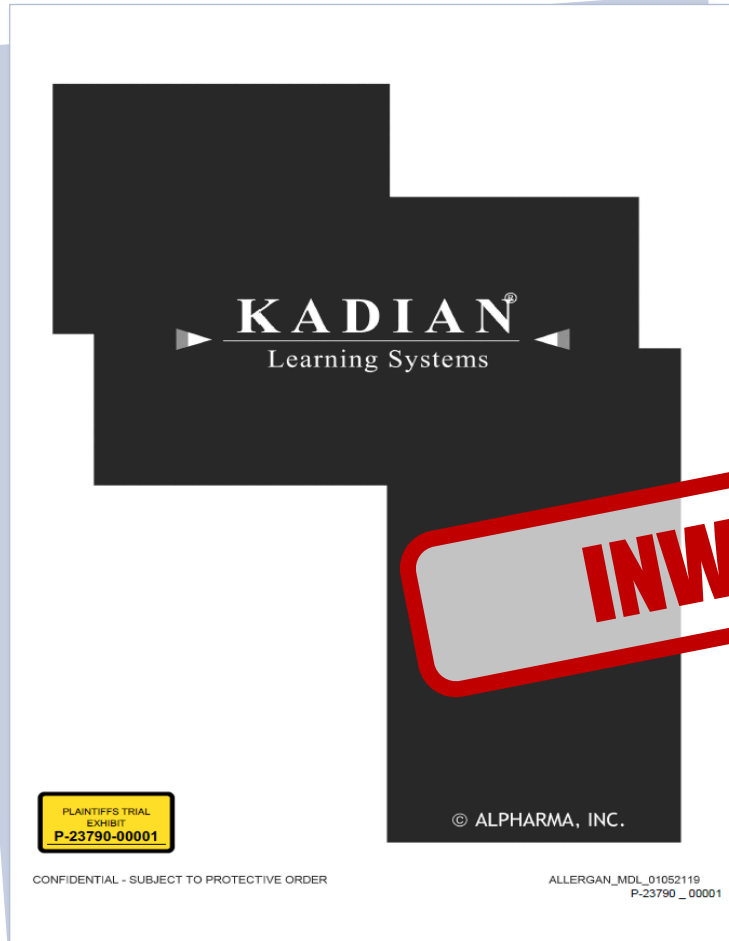
~~Front Groups~~

~~FSMB~~

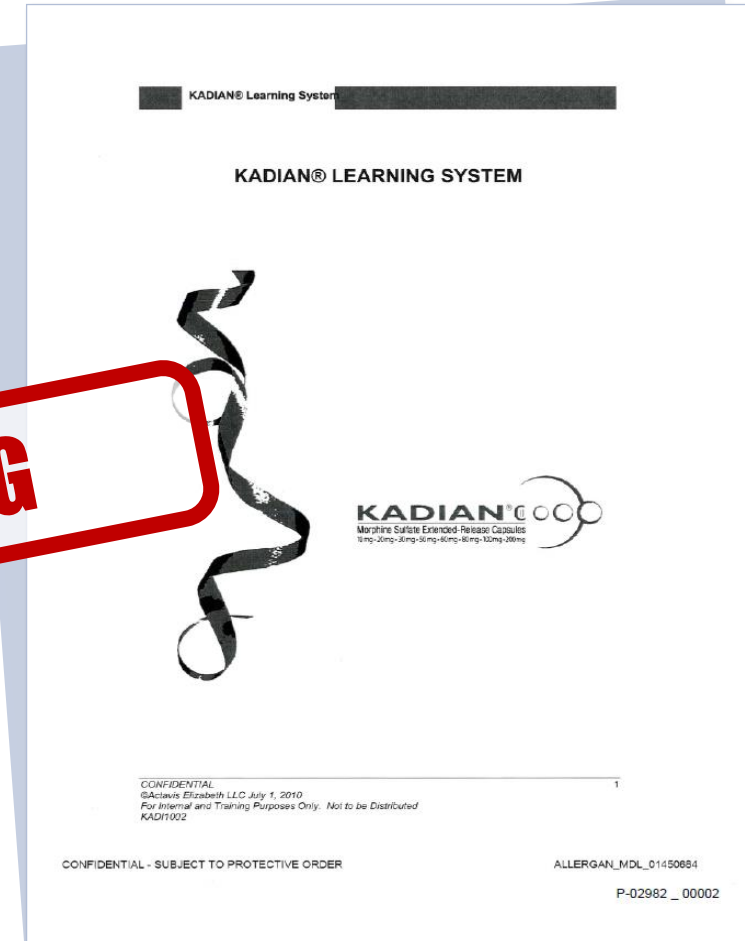
~~California  
Opioid Related  
Legislation~~

~~Joint Commission~~

# Kadian Learning System



P-23790.00001  
P-27812.00195



P-02982.00002  
P-27812.00003

Allergan Defendants Court Exhibit 00001.00012

# Kadian Sales Representative Depositions

**NO**

**Carl  
Balzanti**

**NO**

**Shelley  
Fitch**

**NO**

**Robin  
Hagy**

**NO**

**Debbie  
Webb**

**NO**

**Adriana  
Knoblauch**

Highly Confidential - Subject to Further Confidentiality Review

1 SUPERIOR COURT OF THE STATE OF CALIFORNIA  
2 IN AND FOR THE COUNTY OF ORANGE  
3  
4 THE PEOPLE OF THE STATE  
5 OF CALIFORNIA, acting by  
6 and through Santa Clara  
7 County Counsel James R.  
8 Williams, Orange County  
9 District Attorney Tony  
10 Bacharach, Los Angeles  
11 County Counsel Mary C.  
12 Winkham, and Oakland City  
13 Attorney Barbara J. Parker,  
14 Plaintiffs,  
15  
16 -v- Case No.  
17 30-2014-00721287-CV-ST-CAC  
18 FORNIO PHARMA, L.P., Removable Peter J. Wilson  
19 FORNIO PHARMA, INC., Dep. J. 0210  
20 THE FORNIO PHARMACEUTICAL  
21 COMPANY, INC., TIVA  
22 PHARMACEUTICAL INDUSTRIES,  
23 LTD, TIVA PHARMACEUTICALS  
24 USA, INC., CHORALUX, INC.,  
25 JONSON & JONSON, JANSSEN  
26 PHARMACEUTICAL, INC.,  
27 OTC-MANUEL-JANSSEN  
28 PHARMACEUTICAL, INC. a/k/a  
29 JANSSEN PHARMACEUTICALS,  
30 INC., JANSSEN PHARMACEUTICALS,  
31 INC. a/k/a JANSSEN  
32 PHARMACEUTICAL, INC.,  
33 BMS HEALTH SOLUTIONS INC.,  
34 BMS PHARMACEUTICALS, INC.,  
35 ACTIVIA P&G, ACTIVIA, INC.,  
36 WATSON LABORATORIES, INC.,  
37 ACTIVIA LLC, and ACTIVIA  
38 PHARMA, INC. f/a/a WATSON  
39 PHARMA, INC., and BMS I  
40 THROUGH 100, INCUSIVE,  
41 Defendants.  
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# Sales Representative Training Presentations

## Misrepresentations #2



P-02983.00023

## Misrepresentation #4



P-43013.00002

## Misrepresentation #4



P-21431.00001



# Sales Representative Training Presentations

## KADIAN® Marketing Overview Sales Representative Training October, 2011



1

### Boxed Warning/ Important Safety Information

- When speaking to Healthcare Professionals about KADIAN®, it is important to remind them of the box warning and the Important Safety Information, which can be found on the first spread of each of the promotional tactics (Detail Aid, Dosing Guide and Conversion Guide)
- KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance

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ALLERGAN\_MDL\_00028951

P-02983\_00026

## KADIAN® Marketing Overview Sales Representative Training October, 2011



1

### Boxed Warning/ Important Safety Information

- When speaking to Healthcare Professionals about KADIAN®, it is important to remind them of the box warning and the Important Safety Information, which can be found on the first spread of each of the promotional tactics (Detail Aid, Dosing Guide and Conversion Guide)
- KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance

4

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ALLERGAN\_MDL\_00007271  
P-43013\_00005

## KADIAN® Marketing Overview Sales Representative Training July 2012



1

### Boxed Warning/ Important Safety Information

- When speaking to Healthcare Professionals about KADIAN®, it is important to remind them of the box warning and the Important Safety Information, which can be found on the first spread of each of the promotional tactics (Detail Aid, Dosing Guide and Conversion Guide)
- KADIAN® contains morphine sulfate, an opioid agonist and a Schedule II controlled substance

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ALLERGAN\_MDL\_00026509

P-21431\_00004

Allergan Defendants Court Exhibit 00001.00015

# Sales Representative Training Presentations

## KADIAN® Marketing Overview

Sales Representative Training  
October, 2011



### Important

- Do discuss KADIAN® product features described in the PI, including:
  - KADIAN® contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated
  - KADIAN® has a well known side effect profile
  - KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys
  - KADIAN® is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection.

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ALLERGAN\_MDL\_00026843

P-02983 \_ 00018

## KADIAN® Marketing Overview

Sales Representative Training  
October, 2011



### Important

- Do discuss KADIAN® product features described in the PI, including:
  - KADIAN® contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated
  - KADIAN® has a well known side effect profile
  - KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys
  - KADIAN® is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection.

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ALLERGAN\_MDL\_00007308  
P-43013\_00042

## KADIAN® Marketing Overview

Sales Representative Training  
July 2012



### Important

- Do discuss KADIAN® product features described in the PI, including:
  - KADIAN® contains morphine as its active ingredient and has a long history of safety and efficacy when used as indicated
  - KADIAN® has a well known side effect profile
  - KADIAN® provides steady blood levels of morphine sulfate with few peaks and valleys
  - KADIAN® is available in 8 different strengths and can be titrated in 10mg increments. The availability of these 8 doses provides flexibility in dose selection.

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ALLERGAN\_MDL\_00026548  
P-21431 \_ 00043

Allergan Defendants Court Exhibit 00001.00016

# Sales Representative Training Presentations

## KADIAN® Marketing Overview Sales Representative Training October, 2011



### Important

- Do communicate the full product indication
  - Failing to do so implies that KADIAN is indicated for use in a broader range of conditions or patients than has been demonstrated
- Do discuss safety considerations with prescribers during each call
  - KADIAN® is associated with a number of serious risks, many of which are potentially fatal

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ALLERGAN\_MDL\_0002842

P-02983\_00017

## KADIAN® Marketing Overview Sales Representative Training October, 2011



### Important

- Do communicate the full product indication
  - Failing to do so could imply that KADIAN is indicated for use in a broader range of conditions or patients than has been demonstrated
- Do discuss safety considerations with prescribers during each call
  - KADIAN® is associated with a number of serious risks, many of which are potentially fatal

40

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ALLERGAN\_MDL\_00007307  
P-43013\_00041

## KADIAN® Marketing Overview Sales Representative Training July 2012



### Important

- Do communicate the full product indication
  - Failing to do so could imply that KADIAN is indicated for use in a broader range of conditions or patients than has been demonstrated
- Do discuss safety considerations with prescribers during each call
  - KADIAN® is associated with a number of serious risks, many of which are potentially fatal

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ALLERGAN\_MDL\_0002847  
P-21431\_00042

Allergan Defendants Court Exhibit 00001.00017

## What Dr. Lembke Says:

- “Kadian does not have a ceiling or recommended maximal dose.” P-02983\_00007 (Sales representative training presentation slides).

## What The Document Says:

### Efficacy (con't)



- KADIAN® provides convenience and flexibility with once or twice a day dosing.
- KADIAN® doses can be titrated up every other day.
- KADIAN® does not have a ceiling or recommended maximal dose, especially in patients with chronic pain of malignancy. In such cases the total dose of KADIAN should be advanced until the desired therapeutic endpoint is reached or clinically-significant opioid-related adverse reactions intervene.
- KADIAN® has no significant food effect and can be administered without regard to meals for dosing convenience.
- KADIAN® is available as an extended release capsule, but it has 3 modes of administration

# “Speaker Training” Presentation Slides

**NO SPEAKER PROGRAM**

Managing Chronic Pain and the  
Importance of Customizing  
Opioid Treatment

**KADIAN**   
Morphine Sulfate Extended-Release Capsules  
Wang-Xiang-Xiang-Xiang-Xiang-Xiang-Xiang

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ALLERGAN\_MDL\_01741588  
P-01275 \_ 00004

P-01275.00004