



DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL

**Testimony of David Hart, Oregon Department of Justice
Office of the Oregon Attorney General
to the
United States Senate Committee on Finance**

February 23, 2016

Good morning. I'd like to begin by thanking Chairman Hatch, Ranking member Senator Ron Wyden and members of the Committee for allowing me the opportunity to testify on this important issue. My name is David Hart and I am the Assistant Attorney-in-Charge of the Health Fraud Unit/Consumer Protection Section of the Oregon Department of Justice. For more than 15 years I have led investigations relating to pharmaceutical marketing and promotion, both for the State of Oregon, and for bipartisan multistate coalitions of state Attorneys General. Now, under the leadership of Oregon Attorney General Ellen Rosenblum, I pursue cases related to Oregon's growing—and painful—opioid abuse epidemic. Prior to graduating from law school and joining the Oregon Department of Justice, I practiced as a physical therapist for 15 years at hospitals, nursing homes, home health agencies and hospices. In that time period, I worked with thousands of patients with acute and chronic pain. That experience informed my investigations of the marketing and promotion of opioids which is the subject of my testimony this morning.

The causes of the opioid epidemic are many. While my testimony will focus on the effects of opioid marketing and promotion, I do not want to minimize the existence of other factors that helped cause the epidemic. Because the causes are many, so too will be the solutions. My testimony today will also cover some of the things we are doing in Oregon to combat the epidemic that were funded in part with settlement funds from our cases. If the Federal government wants to take action to stop the opioid abuse, I would urge members of this committee to consider adopting the model approach we have taken in Oregon.

In 2007, Oregon was a member of the Executive Committee of a multistate coalition of state Attorneys General that reached a settlement with Purdue Pharma ("Purdue") to resolve allegations that Purdue violated state consumer protection law by misrepresenting OxyContin's risk of addiction and by promoting OxyContin "off-label" for long term treatment of certain chronic pain conditions. OxyContin, an extended release formulation of oxycodone, was first introduced in 1995. Until that time, opioids were largely used to treat acute pain and cancer pain. Many physicians were reluctant to prescribe opioids on a long-term basis for common chronic conditions because of concerns about abuse and addiction. However, while this inhibition was already breaking down before OxyContin was introduced, after its introduction, this breakdown accelerated, fueled in part by Purdue Pharma's aggressive marketing and promotion of the drug. Attached as Exhibit 1

to my written testimony is a copy of the complaint the Oregon Department of Justice filed against Purdue in May of 2007. Virtually identical complaints were filed by 26 other state Attorneys General. In short, our complaints alleged that although OxyContin is a Schedule II narcotic with an abuse profile and addictive qualities similar to morphine, Purdue aggressively promoted OxyContin to doctors, nurses and consumers as a first-choice analgesic for treatment of a wide variety of pain symptoms. While it expanded the market for OxyContin, Purdue avoided and minimized the known risks of OxyContin abuse, addiction and diversion. Purdue failed to adequately warn doctors or consumers of OxyContin's significant risks and failed to take reasonable steps to guard against OxyContin abuse and diversion, instead striving to "educate" doctors and consumers that concerns over abuse, addiction and diversion of OxyContin were misplaced. Purdue's aggressive promotion of OxyContin led to a dramatic increase in OxyContin prescriptions which in turn furthered an increase in OxyContin abuse and diversion from legitimate users to illicit use of OxyContin.

The 2007 multistate consumer protection settlement with Purdue required cessation of unlawful promotion, and required Purdue to identify and stop promoting OxyContin to doctors who improperly prescribed opiates. Attached as Exhibit 2 to my written testimony is a copy of the multistate settlement. However, the settlement did not require Purdue to take sufficient remedial action to correct misinformation that was endemic in the marketplace. At the time of the multistate settlement, I did not fully appreciate the severity of the opioid epidemic and the long lasting effects of Purdue's OxyContin promotion. Had I so known, I would have advocated for a settlement which would have required more extensive remedial action by Purdue to correct the inappropriate prescribing patterns for opioids that Purdue's marketing helped create.

Oregon, like the rest of the nation, has continued to struggle with overprescribing and misuse of prescription opioids. Between 2000 and 2013, there were 2,226 deaths in Oregon due to prescription opioid drug overdose. The mortality rate associated with prescription opioid overdose increased 364% between 2000 and 2006, and though it has decreased since then, it remains 2.9 times higher than in 2000.¹ Results from the 2013-2014 National Survey on Drug Use Health tie Oregon for 4th place among all states in non-medical use of prescription pain relievers, down from 1st among all states in the same 2010-2011 survey.² In 2013, 3.6 million prescriptions for opioid painkillers were dispensed in Oregon, enough for 925 opioid prescriptions for every 1000 residents.³

To ensure that unlawful drug promotion does not further contribute to this problem, the Oregon Department of Justice has been vigilant to monitor opioid marketing and promotion in our state. As part of that effort, we became concerned about the marketing and promotion of Subsys, a sub-lingual fentanyl spray that is more than fifty times more powerful than heroin and is only approved for breakthrough cancer pain. We believed this powerful drug was being deceptively and unconscionably promoted in Oregon. Pursuant to Oregon's Unlawful Trade Practices Act, we issued Investigative Demands to

¹ 4.0 per 100,000 in 2013; 1.4 per 100,000 in 2000.

² <http://www.samhsa.gov/data/sites/default/files/NSDUHStateEST2012-2013-p1/ChangeTabs/NSDUHsaeShortTermCHG2013.htm>

³ Unpublished Oregon PDMP data.

Insys, the manufacturer of Subsys, obtained documents and information from the company, interviewed former sales representatives and consulted with experts. Our comprehensive investigation revealed several patterns of alleged misconduct, including reports that the company provided improper financial incentives to doctors to increase prescriptions, aggressively promoted Subsys to doctors not qualified to prescribe the drug, and deceptively promoted Subsys for treatment of mild pain. After our investigation, we issued a formal Notice of Unlawful Trade Practices which lays out the allegations. In short, Oregon was the first state in the country to allege that Insys promoted Subsys “off-label” for non-cancer pain such as back pain and neck pain, uses for which Subsys is neither safe nor effective. We also outlined allegations that Insys unconscionably targeted problem doctors who misprescribed opiates with aggressive Subsys promotion and that Insys facilitated prescribing of Subsys for contraindicated uses. Not only did Insys target problem opiate prescribers, it hired those doctors to teach other doctors about Subsys. I was truly shocked that in 2015, when the scourge of the opioid epidemic was so widely known, that a manufacturer of a schedule II drug would promote a powerful opioid such as Subsys in such an unconscionable and irresponsible way. Attached to my written testimony as Exhibit 3 is a copy of Notice of Unlawful Trade Practices which describes this conduct in greater detail.

To avoid a lawsuit that would litigate our allegations, Insys agreed to an Assurance of Voluntary Compliance which prohibits the misconduct that we identified in our investigation and required Insys to pay Oregon more than two times the total Subsys sales in the state. Oregon was also the first government entity to settle with Insys for this alleged misconduct. Attached to my written testimony as Exhibit 4 is a copy of the Assurance of Voluntary Compliance.

Fortunately, much of the \$1.1 million dollar payment the Oregon Department of Justice received from the Insys settlement is now being used to fund efforts to address the opioid epidemic in Oregon. This includes:

- Funding regional pain guidance groups to develop opioid prescribing practices for their communities and to facilitate coordination of care across specialties;
- Funding development of regional action plans to prevent opioid abuse;
- Funding addiction treatment training to increase the number of Oregon physicians in underserved communities with the waiver necessary to treat opioid dependent individuals with agonist and partial agonist medications in an office based setting;
- Funding to support addiction treatment telemedicine consultation services to expand access to treatment for Oregonians with substance abuse disorders in the communities where they live;
- Funding to promote disposal of unused and expired opioids by helping pharmacies become licensed disposal locations;
- Funding to expand the use of Naloxone, a drug that reverses the lethal effects of an opioid overdose; and
- Funding to build a statewide pain guidance public education campaign web platform with regional resource pages to help providers, patients and family members make informed choices.

It is our hope in Oregon that these programs and initiatives will save lives. We also hope that other states, and the Federal government, will consider programs like the one in Oregon that take a holistic—and realistic—approach to fighting our country's opioid epidemic.

This concludes my testimony. Again, thank you Chairman Hatch, Ranking member Senator Ron Wyden and members of the Committee for inviting me today. I am available to answer questions.

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ENTERED
MAY 08 2007
Marion County Circuit Court

STATE OF OREGON
Marion County Circuit Courts
MAY 08 2007
FILED

IN THE CIRCUIT COURT OF THE STATE OF OREGON
FOR THE COUNTY OF MARION

STATE OF OREGON ex rel HARDY
MYERS, Attorney General for the State of
Oregon,

Plaintiff,

v.

PURDUE PHARMA L.P.,
PURDUE PHARMA INC., dba
PURDUE FREDERICK COMPANY,

Defendants.

Case No. 07C14241

COMPLAINT ALLEGING VIOLATIONS OF
THE UNLAWFUL TRADE PRACTICES ACT
(ORS 646.605 TO 646.656)

CLAIM NOT SUBJECT TO MANDATORY
ARBITRATION

This complaint alleges claims for relief based upon violation of Oregon's Unlawful Trade Practices act (UTPA), ORS 646.605 to 646.656. Plaintiff, State of Oregon for its Complaint alleges that at all times material herein:

1.

HARDY MYERS is the Attorney General for the State of Oregon and is suing in his official capacity pursuant to ORS 646.632.

2.

Defendant Purdue Pharma L.P. is a limited partnership with its principal place of business at One Stamford Forum, Stamford, Connecticut. At all times relevant to this Complaint, Purdue Pharma L.P. has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing OxyContin throughout the United States, including the state of Oregon.

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3.

Defendant Purdue Pharma Inc. is a Delaware corporation with its principal place of business at One Stamford Forum, Stamford, Connecticut. At all times relevant to this Complaint, Purdue Pharma Inc. has been in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and/or distributing OxyContin throughout United States, including the State of Oregon. Purdue Pharma Inc. is the general partner of Purdue Pharma, L.P., and at all relevant times has supervised and managed the operations and affairs of its subsidiary and affiliate, Purdue Pharma, L.P.

4.

The conduct alleged in this Complaint concerns all defendants who henceforth are referred to collectively as Purdue

5.

The Circuit Court for the State of Oregon has personal jurisdiction over Purdue pursuant to ORCP 4A. Purdue engaged insubstantial activities within Oregon by operating a business that provides services that are primarily for personal, family, and household use. All transactions took place in the course of Purdue's business.

6.

Prior to filing this Complaint, Purdue waived receipt of the notice required by ORS 646.632(2) that they had engaged in unlawful trade practices and the relief sought. Purdue has not delivered an Assurance of Voluntary Compliance that complies with the requirements contained in ORS 646.632.

7.

The conduct of Purdue described in this Complaint was willful within the meaning of ORS 646.605(10).

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1 SUMMARY OF THE ACTION

2 8.

3 This civil action arises out of Purdue’s unfair and deceptive marketing of the opioid
4 painkiller OxyContin. Although OxyContin is a Schedule II narcotic with an abuse profile and
5 addictive qualities similar to morphine, Purdue aggressively promoted OxyContin to doctors,
6 nurses and consumers as a first-choice analgesic for treatment of a wide variety of pain
7 symptoms. While it expanded the market for OxyContin, Purdue avoided and minimized the
8 known risks of OxyContin abuse, addiction and diversion. Purdue failed to adequately warn
9 doctors or consumers of OxyContin’s significant risks and failed to take reasonable steps to
10 guard against OxyContin abuse and diversion, instead striving to “educate” doctors and
11 consumers that concerns over abuse, addiction and diversion of OxyContin were misplaced.
12 Purdue’s aggressive promotion of OxyContin led to a dramatic increase in OxyContin
13 prescriptions, which in turn furthered an increase in OxyContin abuse and diversion from
14 legitimate users to illicit use of OxyContin.

15 FACTS

16 **Purdue Manufactures and Sells OxyContin, a Schedule II Narcotic Opioid**
17 **Designed to Treat Serious, Long-Term Pain**

18 9.

19 OxyContin is an opioid analgesic - a narcotic substance that relieves a person’s
20 pain without causing the loss of consciousness. OxyContin is a controlled-release form of
21 oxycodone hydrochloride. Oxycodone is a very powerful pain reliever similar to morphine and
22 is the active ingredient in OxyContin as well as oxycodone-combination drugs such as Percocet,
23 Percodan and Tylox.

24 10.

25 Purdue developed and manufactures OxyContin. OxyContin’s controlled release of
26 oxycodone purports to facilitate 12-hour dosing for OxyContin, which distinguished it from

1 other oxycodone tablets typically administered in 4 to 6 hour doses. Due in part to its controlled-
2 release feature, OxyContin contains more oxycodone than other oxycodone drugs.

3 11.

4 OxyContin is a Schedule II narcotic, which means its manufacture and
5 distribution is subject to the Drug Enforcement Agency's ("A DEA") regulation and control.
6 Classification of OxyContin as a Schedule II controlled substance means that the DEA has
7 determined that OxyContin: i) has a high potential for abuse, ii) has been accepted for medical
8 use in the United States subject to severe restrictions, and iii) abuse may lead to severe
9 psychological or physical dependence.

10 12.

11 As reflected by the DEA's oversight, OxyContin has an abuse profile, and
12 addictive qualities, similar to morphine. Among other things, this means that: first, OxyContin
13 users experience euphoria, making the drug prone to abuse (*i.e.*, non-medical use); second,
14 OxyContin causes physical dependence, meaning that a user will experience withdrawal
15 symptoms upon terminating use; and third, tolerance is common, meaning that, over time,
16 dosage often must increase in order to provide the same level of pain relief.

17 13.

18 In sum, opioids like OxyContin cause physical dependence and are prone to abuse
19 and addiction. As a result, doctors have traditionally, and correctly, exercised caution in
20 prescribing opioids, weighing their analgesic effect against the risks of dependence, addiction,
21 abuse, and diversion from legitimate patients to illicit, non-medical use.

22 14.

23 Although OxyContin posed the same risks as MS Contin and other opioids,
24 Purdue, as part of its marketing strategy, sought to position OxyContin differently from other
25 opioids by avoiding or minimizing the drug's known risks.

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15.

In December 1995, the FDA approved the use of OxyContin for the following “indications,” that is, the circumstances for which the FDA has determined that a drug is safe and effective:

Indications: “OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate-to-severe pain where use of an opioid analgesic is appropriate for more than a few days.”

16.

In 2001, the FDA changed the OxyContin indications. OxyContin is now indicated for the “management of moderate-to-severe pain *when a continuous around-the-clock analgesic is needed for an extended period of time.*”

17.

Since 1995, the FDA also has restricted the appropriate marketing and use of OxyContin as reflected in the OxyContin label. Among other things, the FDA has determined that OxyContin, because it has not been shown to be safe and effective for these uses, should not be promoted:

- for use as a prn analgesic. “Prn” means as needed, or as required.
- for use as a preemptive analgesia (pre-operative), that is, not to be administered in advance of an operation for expected pain.
- for post-operative pain in patients not already on OxyContin.
- for post-operative pain unless the pain is moderate-to-severe and expected to persist for extended period.
- where contraindicated for patients with significant respiratory depression, acute or severe bronchial asthma or hypercarbia, or with paralytic ileus.

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1 **Purdue Promoted OxyContin through a**
2 **Multifaceted Marketing Campaign**

3 18.

4 Purdue has marketed OxyContin to doctors, dentists, nurses, other healthcare
5 professionals, and patients. Purdue's goals have been to increase the number of doctors
6 prescribing OxyContin, increase the number of patients taking OxyContin, and increase the
7 OxyContin dosages prescribed by doctors, all in order to increase OxyContin sales and generate
8 profits for Purdue.

9 19.

10 Purdue has, at various times:

- 11 a) employed hundreds of sales representatives paid to visit with doctors, nurses,
12 pharmacists and other health care professionals to expand the prescription writing
13 base and increase prescription writing for OxyContin;
- 14 b) prepared and distributed sales aids, visuals, hand outs, and "leave behind"
15 promotional items to be used by sales representatives and distributed to healthcare
16 professionals;
- 17 c) conducted seminars, trainings and purported educational programs for health care
18 professionals to promote treatment of pain via increased opioid usage, specifically
19 OxyContin;
- 20 d) placed OxyContin advertisements in medical journals and other publications
21 directed at healthcare professionals;
- 22 e) maintained websites directed at patients, patient families, and healthcare
23 professionals promoting pain treatment, specifically via prescribing OxyContin or
24 other opioids;

25 20.

26 Purdue's sales efforts are directed to: i) get doctors to prescribe and nurses to recommend
OxyContin, ii) ensure that hospitals and managed care organizations place OxyContin on their
drug formularies and treat it favorably vis-a-vis other painkillers, iii) encourage pharmacies to
stock OxyContin, in all prescription strengths, and iv) encourage hospitals and long term care
facilities to purchase and use OxyContin for their patients.

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21.

The bulk of sales representatives' efforts focus on visiting doctors, nurses and other medical staff. Purdue provides its sales representatives with precise information on doctors' prescribing histories for OxyContin and other opioid painkillers. Armed with this information, Purdue and its sales representatives identify "core" physicians and "A-1" sales targets, who are deemed to be actual or potential high-volume prescribers of OxyContin.

22.

Purdue sales representatives visited these doctors and their staffs to encourage use of OxyContin. If a doctor prescribed opioids other than OxyContin, Purdue sales reps encouraged them to switch to OxyContin. If a doctor already prescribed OxyContin, Purdue sales representatives encouraged OxyContin for more patients, for broader uses, and in increased dosages or strengths.

23.

Purdue linked sales representatives' compensation directly to increased OxyContin prescribing by those doctors and institutions in the representatives' territory, as discussed further below.

24.

Purdue designed its seminars, trainings and "educational" programs for doctors, pharmacists and nurses to serve the same goals as Purdue's office sales visits: promote OxyContin as the opioid of choice, get healthcare professionals "comfortable" with prescribing high strength narcotic opioids, and ultimately increase OxyContin prescriptions.

25.

Regardless of the promotion medium, Purdue and its sales representatives echoed several simple OxyContin sales messages consistently reflected in Purdue's advertisements, marketing plans, and instructions to sales representatives. With respect to encouraging doctors to prescribe OxyContin, Purdue sought to:

- “enhance the acceptance of opioids for non-cancer pain,” and, with respect to OxyContin, avoid any stigma attached to use of opiates;
- expand OxyContin tablets use in non-malignant pain market by positioning it as “the one to start with and the one to stay with;”
- establish OxyContin as the first-line choice at Step 2 of the WHO pain ladder (mild to moderate pain);
- increase the use of OxyContin tablets for a wide variety of conditions, and for acute and sub-acute pain (e.g., “post-op pain, trauma, fractures”); and
- encourage assessment of pain by physicians and communication of pain by patients, and attach an emotional aspect to non-cancer pain so physicians treat it more aggressively.

26.

With respect to the characteristics of OxyContin itself, Purdue’s marketing emphasized:

- that OxyContin is strong (“It Works”);
- the duration of pain control -- that unlike other oxycodone medication, OxyContin need only be taken every 12 hours;
- the convenience of 12 hour dosing as compared to 4 or 6 hour analgesics (print ads showing six dosage cups vs. two and stating “the hard way vs. the easy way”);
- that OxyContin acts quickly - that the onset of analgesia is within one hour in most patients; and
- that OxyContin was appropriate for a wide range of patients.

27.

Purdue promoted OxyContin to a wide variety of doctors, without regard for their training or experience prescribing opioids, encouraging OxyContin for an ever-increasing list of conditions, and patient types. While expanding the market in this way, Purdue failed to adequately account for known health and safety risks of OxyContin, especially the risks of OxyContin abuse, dependence, addiction and diversion.

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1 **Purdue's Marketing Strategy was to Steadily Expand OxyContin Usage**
2 **from Cancer Pain Treatment to a Wide Array of Ailments**

3 28.

4 At the outset of the OxyContin launch, Purdue briefly marketed OxyContin principally
5 for treatment of chronic pain in cancer patients. That quickly changed. Beginning in 1996,
6 Purdue consistently expanded: a) the types of doctors and healthcare professionals to whom it
7 promotes OxyContin; b) the classes of patients for whom it encourages OxyContin to be
8 prescribed; and c) the array of diseases and types of pain for which it promotes OxyContin use.

9 29.

10 One step in Purdue's plan to expand OxyContin use to all sorts of pain was its decision to
11 focus its sales efforts on primary care physicians ("PCPs").

12 30.

13 Purdue targeted PCPs as a fruitful avenue to increased OxyContin sales. Sales
14 representatives visited thousands of primary care physicians and sought to convince them that
15 OxyContin was an appropriate first-line painkiller for a wide variety of ailments. More than half
16 of doctor visits by Purdue sales reps were to PCPs. The aggressive marketing to PCPs paid off:
17 Since 2002, PCPs have accounted for nearly half of all OxyContin prescriptions.

18 31.

19 Purdue's promotional efforts also targeted additional types of physicians, eventually
20 including surgeons, gerontologists, rheumatologists, orthopedics, arthritis specialists,
21 obstetricians and gynecologists, emergency medicine physicians, and dentists. Purdue failed to
22 take meaningful steps to educate these doctors on the risks of opioid use, abuse, addiction and
23 diversion. Instead, Purdue repeated its simple sales messages: pain is undertreated, OxyContin
24 provides easy dosing and prompt relief, and is the "one to start with and to stay with."

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32.

Purdue consistently expanded the pain ailments for which it aggressively promoted OxyContin, without a concomitant focus on limiting OxyContin to serious and prolonged pain.

33.

As Purdue's promotional activities expanded the proposed uses for OxyContin - to include many diseases and many types of pain - Purdue's marketing strategy minimized OxyContin's risks. Instead of recommending caution in the use of a Schedule II narcotic with an abuse profile similar to morphine, Purdue in essence pitched OxyContin as simply a powerful pain reliever - for many types of pain and for many types sorts of patients - with few precautions to guard against its capacity for abuse, dependence, addiction and diversion.

34.

Purdue also failed to closely follow appropriate step therapy and instead promoted OxyContin as the first-line pain reliever that could be used to treat all levels of pain – “the one to start with and stay with” and “the easy way.”

35.

Purdue's sales strategy to expand OxyContin's prescriber base and patient population was successful. Within years of its launch and through the present, OxyContin was and is prescribed by a wide range of doctors for a wide range of pain ailments.

**While Expanding the Prescriber Base and Usage of OxyContin,
Purdue Failed to Adequately Focus on OxyContin's Health and Safety Risks,
Especially the Risks Related to Abuse and Diversion**

36.

From its product launch, Purdue knew that OxyContin was prone to abuse, dependence, addiction and diversion. But the linchpin of Purdue's marketing strategy was to distinguish OxyContin from other opioids and their well known risk of abuse, and to avoid the stigma attached to these other opioids, particularly morphine. Purdue's sales strategy focused on getting

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1 doctors “comfortable” with prescribing OxyContin, even though prescribing opioids warrants
2 that doctors exercise caution, and OxyContin did not warrant different treatment.

3 37.

4 In 2001, amidst significant media coverage of widespread OxyContin abuse, diversion
5 and addiction, the FDA required Purdue to significantly alter its label to provide a so-called
6 “black box” warning, including the following:

7 *Warning: OxyContin is an opioid agonist and a Schedule II controlled*
8 *substance with an abuse liability similar to morphine.*
9 *OxyContin Tablets are to be swallowed whole, and are not to be broken,*
10 *chewed or crushed. Taking broken, chewed or crushed OxyContin Tablets leads*
11 *to rapid release and absorption of a potentially fatal dose of oxycodone.*

12 38.

13 Even after the FDA required Purdue to bolster its OxyContin warning, Purdue continued
14 to minimize the risks of abuse, addiction and diversion in its marketing. Instead, Purdue
15 repeated its message that pain is undertreated, that patients deserve opioid treatment, and that
16 OxyContin is the answer. Any meaningful message on the risks of abuse, addiction and
17 diversion would have undermined Purdue’s sales objectives, and Purdue avoided it.

18 39.

19 Purdue sought to portray “addiction” to opioids as exceedingly rare. By way of example,
20 Purdue’s videotape “From One Patient to Another,” advised patients that “Less than 1% of
21 patients taking opioids actually become addicted.” A Purdue pamphlet entitled “Counseling
22 Your Patients and Families Regarding the Use of Opioids,” stated: “Many patients and family
23 members - will be surprised to discover that fewer than 1% of opioid-using patients become
24 addicted.” Purdue’s focus on “addiction,” narrowly defined, to the exclusion of broader concepts
25 of psychological dependence, physical dependence, tolerance and abuse, made its representations
26 misleading.

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40.

If doctors expressed concern over using OxyContin due to its capacity for abuse, dependence or addiction, Purdue trained its sales representatives to avoid and minimize those concerns.

41.

Although Purdue, in response to public scrutiny of widespread OxyContin abuse, has claimed to implement programs designed to guard against diversion and abuse, it has continued to try to convince doctors that their concerns of addiction, dependence and abuse are misplaced.

Purdue Employed a Sales Approach and Incentive System that Exacerbated, Rather Than Guarded Against, the Risk of OxyContin Abuse, Addiction and Diversion

42.

Purdue sales representatives were compensated in large measure for increasing the volume of OxyContin prescribed and sold. Purdue's sales goals were plain: to increase the number of doctors prescribing Oxycontin, to increase the number of prescriptions written by each, and to increase dosages of OxyContin. Purdue's sales approach and incentive system failed to adequately balance Purdue's desire for increased OxyContin sales with safeguards against OxyContin abuse, addiction and diversion.

43.

Both through its compensation structure and through its sales managers, Purdue cultivated a high pressure environment for its sales representatives. This pressure to increase sales was not properly balanced against public safety and failed to account for the known risks of OxyContin.

44.

Purdue also instructed its sales representatives to focus their sales efforts on those doctors who already prescribed the greatest amount of OxyContin, urging them to write more prescriptions for more patients. Using detailed prescribing data on doctors, Purdue sales

1 representatives strove to increase “new starts” and increase prescription volume by these key
2 prescribers.

3 45.

4 These aspects of Purdue’s sales and incentive system all served to promote, not guard
5 against, OxyContin abuse, diversion and addiction.

6 46.

7 Purdue also failed to use its detailed prescribing information on doctors to guard against
8 OxyContin abuse and diversion. Purdue, since OxyContin’s launch, purchased detailed
9 prescribing data from IMS Health (“IMS data”), showing the prescribing history and patterns of
10 doctors, including the number of OxyContin prescriptions written, the dosages, as well as the
11 same prescribing information with respect to competing opioids and other drugs. Purdue
12 provides each sales representative this prescribing information for target doctors in their
13 territory.

14 47.

15 Purdue could have used the prescribing data to readily identify potential sources of abuse
16 and diversion, such as “pill mills” that divert OxyContin to the illicit street market. Purdue then
17 could have employed meaningful internal measures to guard against abuse and diversion risks.
18 For instance, Purdue could have visited those doctors to review pain documentation practices or
19 otherwise protect against potential abuse or diversion. Or, the company could have shared with
20 law enforcement those prescribing patterns that evidenced a risk of abuse or diversion. For
21 years, Purdue did not take those steps.

22 48.

23 Purdue, notwithstanding its marketing claims focused on fighting abuse and diversion,
24 declined to use the IMS prescribing data to protect against abuse and diversion risks. Purdue
25 sales representatives instead targeted the highest prescribers and encouraged them to prescribe
26 ///

1 more OxyContin, in larger doses, to more patients. Purdue's marketing practices thus
2 exacerbated the abuse and diversion risks.

3 49.

4 Purdue's OxyContin marketing resulted in dramatic increases in OxyContin
5 prescriptions.

6 **CAUSE OF ACTION**

7 **UNLAWFUL TRADE PRACTICES**

8 **ORS 646.608(1)(e)**

9 50.

10 Plaintiff, STATE, realleges and incorporates each and every allegation contained in the
11 preceding paragraphs as if fully alleged herein.

12 51.

13 Purdue violated ORS 646.608(1)(e) by

- 14 a) aggressively marketing OxyContin to a broad variety of doctors and patients, for
15 an ever expanding array of ailments, sometimes contrary to its label and
16 indications, while failing to adequately disclose and reasonably warn of and guard
17 against the health and safety risks associated with OxyContin, including the risks
18 associated with misuse, abuse, dependence, addiction and diversion;
- 19 b) avoiding or minimizing the known risks of OxyContin, including the risks of abuse,
20 dependence, addiction and diversion; and

21 **PRAYER FOR RELIEF**

22 WHEREFORE, Plaintiff respectfully request that a judgment be entered that:

23 A. Permanently enjoins Purdue from making any false, misleading or deceptive
24 representation regarding its products in violation of all applicable laws and regulation.

25 B. Directs Purdue to comply with all applicable laws and regulations relating to the
26 marketing, sale, and promotion of its products.

27 ///

1 C. Directs Purdue to pay civil penalties for each willful violation of ORS
2 646.608(1)(e)

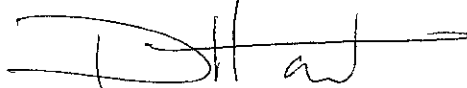
3 D. Awards Plaintiffs costs and attorneys fees, pursuant to ORS 646.632 (8);

4 E. Grants all other relief as the Court deems appropriate.

5 Dated May 8, 2007.

6 Respectfully submitted,

7 HARDY MYERS
8 Attorney General

9 

10 David A. Hart, OSB No. 00275
11 Assistant Attorney General
12 1162 Court Street, N.E.
13 Salem, OR. 97301-4096
14 (503) 947-4333
15 Of Attorneys for Plaintiffs

STATE OF OREGON
Marion County Circuit Courts
MAY 08 2007
FILED

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2
3
4 IN THE CIRCUIT COURT OF THE STATE OF OREGON
5 FOR THE COUNTY OF MARION

6 STATE OF OREGON ex rel HARDY
7 MYERS Attorney General for the State of
8 Oregon,

9 Plaintiff,

10 v.

11 PURDUE PHARMA L.P.; PURDUE
12 PHARMA, INC. d/b/a PURDUE
13 FREDERICK COMPANY,

14 Defendants.

Case No. 07C14241

STIPULATED GENERAL JUDGMENT

15 Plaintiff, State of Oregon, acting by and through Attorney General Hardy Myers has
16 brought this action pursuant to ORS 646.632, having filed a complaint against the Defendant
17 Purdue Pharma L.P. and the parties having consented to the entry of this Stipulated General
18 Judgment (hereinafter referred to as "Judgment") for the purpose of settlement only, without trial
19 of any issue of fact or law, NOW THEREFORE, upon the consent of the parties hereto
20 IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

21 This Judgment is entered into between the Attorneys General or other entities¹ of the
22 States and Commonwealths of Arizona, Arkansas, California, Connecticut, District of Columbia,

23 ¹ For the purposes of this agreement, when the entire group is referred to as "Signatory Attorneys
24 General," such designation, as it pertains to CONNECTICUT, shall refer to the Commissioner of
25 the Department of Consumer Protection, who enters this Consent pursuant to the Connecticut
26 Unfair Trade Practices Act, Conn. Gen. Stat. Sec. 42-110j, acting by and through his counsel,
Richard Blumenthal, Attorney General for the State of Connecticut. For MONTANA, such
designation shall refer to the Consumer Protection Office of the Department of Justice who
enters into this settlement pursuant to the Montana Unfair Trade and Consumer Protection Act of
1973 MCA 30-14-101 *et al.*, acting by and through his counsel, Mike McGrath, Attorney
General for the State of Montana.

1 Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, Nebraska,
2 Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee,
3 Texas, Vermont, Virginia, Washington, and Wisconsin (hereinafter referred to as "Signatory
4 Attorneys General"), acting on behalf of their respective states, and pursuant to their respective
5 consumer protection statutes; and Purdue Pharma L.P., et al (hereinafter referred to as "Purdue").

6 **I. DEFINITIONS**

7 1. The following definitions shall be used in construing this Judgment

8 A. "Covered Persons" shall mean all officers, employees and all contract or third-
9 party sales representatives, including Medical Liaisons, of Purdue or retained by Purdue having
10 direct responsibility for marketing and promoting OxyContin to Health Care Professionals.

11 B. "Effective Date" shall mean the date on which Purdue receives a copy of this
12 Judgment, duly executed by Purdue and by the Signatory Attorney General and filed with the
13 Court.

14 C. "FDA Guidances for Industry" shall mean documents published by the United
15 States Department of Health and Human Services, Food and Drug Administration ("FDA") that
16 represent the FDA's current recommendations on a topic.

17 D. "Health Care Professional" or "Health Care Professionals" shall mean any person
18 or persons duly licensed by relevant federal and/or state law to prescribe Schedule II
19 pharmaceutical products, as well as duly licensed pharmacists, nurses and other licensed health
20 professionals.

21 E. "Off-Label Promotion" shall mean the marketing and promotion of an Off-Label
22 Use. Off-Label Promotion shall not mean discussion of the abuse and diversion of OxyContin
23 that is not inconsistent with the Package Insert.

24 F. "Off-Label Use" shall mean any use inconsistent with the "Indications and
25 Usage" section of the Package Insert.

26

1 G. "OxyContin" shall mean any controlled-release drug distributed by Purdue which
2 contains oxycodone as an active pharmaceutical ingredient.

3 H. "Package Insert" shall mean the FDA approved label (as described in 21 C.F.R.
4 §§ 201.56 and 57) for OxyContin, including all modifications to the label theretofore approved
5 by the FDA.

6 I. "Parties" shall mean Purdue and the Signatory Attorneys General.

7 J. "Purdue" shall mean Purdue Pharma L.P., Purdue Pharma Inc., The Purdue
8 Frederick Company Inc (d/b/a/ The Purdue Pharma Company), and all of their United States
9 affiliates, subsidiaries, predecessors, successors, parents and assigns, who manufacture, sell,
10 distribute and/or promote OxyContin.

11 K. "Remuneration" shall mean any gift, fee, or payment, exceeding twenty-five
12 dollars (\$25.00) in value, provided by Purdue directly or indirectly in connection with marketing
13 or promotion of OxyContin.

14 L. "Signatory Attorney General" shall mean the Attorney General, or his or her
15 designee, who has agreed to this Judgment.

16 M. "Subject Matter of this Judgment" shall mean the investigation under the State
17 Consumer Protection Laws² of Purdue's promotional and marketing practices regarding
18 OxyContin.

19 _____
20 ² ARIZONA Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et seq.*; ARKANSAS - Deceptive
21 Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and
22 Professions Code § 17200 *et seq* 17500 *et seq* ; CONNECTICUT – Connecticut Unfair Trade
23 Practices Act, Conn. Gen. Stat. §42-110 *et seq.*; DISTRICT OF COLUMBIA – District of
24 Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.*; IDAHO -
25 Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS - Consumer Fraud and
26 Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2002); KENTUCKY - Consumer
Protection Statute, KRS 367.170; LOUISIANA – Unfair Trade Practices and Consumer
Protection Law, LSA-R.S. 51:1401 *et seq.*; MAINE – Unfair Trade Practices Act, 5 M.R.S.A.
section 205-A *et. seq*; MARYLAND - Consumer Protection Act, Maryland Commercial Law
Code Annotated § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c.
93A *et seq.*; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEBRASKA – Consumer
Protection Act: Neb.Rev.Stat. 59-1601, *et seq.* (Reissue 2004 & RS Supp. 2006), Uniform

1 **II. COMPLIANCE PROVISIONS**

2 2. In the promotion and marketing of OxyContin, Purdue shall not make any written
3 or oral claim that is false, misleading or deceptive.

4 3. In the promotion and marketing of OxyContin, Purdue shall not market or
5 promote OxyContin in a manner that is, directly or indirectly, inconsistent with the "Indication
6 and Usage" section of the Package Insert for OxyContin. Further, Purdue shall, consistent with
7 the Package Insert, or as otherwise permitted by the FDA, not promote or market OxyContin in
8 a manner that: (a) avoids or minimizes the fact that OxyContin is indicated for moderate to
9 severe pain when a continuous around-the-clock analgesic is needed for an extended period of
10 time; or (b) avoids, minimizes, or is inconsistent with individualizing treatment using a plan of
11 pain management, such as outlined by the World Health Organization, the Agency for
12 Healthcare Research and Quality (formerly known as the Agency for HealthCare Policy and
13 Research), the Federation of State Medical Boards Model Guidelines or the American Pain
14 Society, as referenced in the Package Insert.

15 4. In the promotion and marketing of OxyContin, Purdue shall provide "fair
16 balance" statements, as defined in 21 C.F.R. §202.1 as may be amended or supplemented, or as
17 appearing in FDA Guidances for Industry from time to time, regarding contraindications and
18

19
20 Deceptive Trade Practices Act: Neb.Rev.Stat. 87-301 *et seq.* (Reissue 1999 & RS Supp. 2006);
21 NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW
22 MEXICO - Unfair Practices Act" NMSA 1978, S 57-12-1 *et seq.* (1967); NORTH CAROLINA
23 - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; OHIO - Consumer Sales
24 Practices Act, R.C. § 1345.01 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605
25 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. §
26 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, Sections 39-5-10 *et seq.*;
TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS
- Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et*
seq., (Vernon 2002); VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA -
Virginia Consumer Protection Act, Va.Code Ann. § 59.1 -196 *et seq.*; WASHINGTON -
Washington Consumer Protection Act - R.C.W. 1986 *et seq.*; WISCONSIN - Wis. Stat. § 100.18
(Fraudulent Representations).

1 adverse events, including but not limited to statements regarding OxyContin's potential for
2 abuse, addiction, or physical dependence as set forth in the Package Insert.

3 5. In the promotion and marketing of OxyContin, Purdue shall not make
4 misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical
5 dependence as set forth in the Package Insert. Further to this general prohibition on
6 misrepresentations, Purdue, in the promotion and marketing of OxyContin, shall not represent,
7 except as may be set forth in the Package Insert, that: a) OxyContin is "nonaddictive" or
8 "virtually nonaddictive"; b) addiction to OxyContin occurs in "less than 1%" of patients being
9 treated with OxyContin; or c) OxyContin's potential for abuse, addiction or physical dependence
10 differs from any other Schedule II opioid analgesic.

11 6. In the promotion and marketing of OxyContin, Purdue shall not make any written
12 or oral promotional claim of safety or effectiveness for Off-Label Uses of OxyContin in a
13 manner that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and
14 accompanying regulations as may be amended or supplemented, or as appearing in FDA
15 Guidances for Industry from time to time.

16 7. Except upon a request for such information without solicitation by Purdue to
17 make the request, Purdue shall not provide to Health Care Professionals written materials
18 describing the Off-Label Use of OxyContin that have not appeared in a scientific or medical
19 journal or reference publication or any portion thereof. Purdue shall maintain records for three
20 (3) years of the identity of all Health Care Professionals to whom such materials relating to the
21 Off-Label Use of OxyContin have been provided. "Scientific or medical journal" is a
22 publication whose articles are published in accordance with regular peer-reviewed procedures;
23 that uses experts to review or provide comment on proposed articles; and that is not in the form
24 of a special supplement that has been funded in whole or in part by one or more manufacturers.
25 "Reference publication" is a publication that has no common ownership or other corporate
26 affiliation with a pharmaceutical or medical device manufacturer; that has not been written,

1 edited, excerpted, or published specifically for, or at the request of, such a manufacturer; and that
2 has not been edited or significantly influenced by such a manufacturer.

3 8. A. When Purdue provides an individual or entity with any educational grant,
4 research grant, or other similar Remuneration relating to OxyContin, Purdue shall obtain the
5 recipient's agreement: (i) to clearly and conspicuously disclose the existence of said funding or
6 Remuneration to the readers of any resulting letter, study, research or other materials which was
7 supported by said funding or Remuneration, and (ii) to refund said funding or Remuneration if
8 such disclosure is not made.

9 B. Purdue shall require that a recipient of any Remuneration from Purdue for the
10 promotion of OxyContin agree: (i) to clearly and conspicuously disclose the existence, nature
11 and purpose of the Remuneration to the participants in any educational event at which the
12 recipient discusses an Off-Label Use of OxyContin, and (ii) to refund said Remuneration if such
13 disclosure is not made.

14 C. Purdue shall itself clearly and conspicuously disclose the existence of any grant or
15 other form of Remuneration that it has provided for the publication of a letter, study, research or
16 other material relating to OxyContin when Purdue disseminates or refers to said letter, study,
17 research or other material in communications with Health Care Professionals.

18 9. Purdue shall comply with all applicable Accreditation Council for Continuing
19 Medical Education ("ACCME") Guidelines.

20 10. Purdue shall comply with paragraphs 2, 3, 4, 5, 7 and 8 of the Pharmaceutical
21 Research and Manufacturers of America Code (effective on July 1, 2002) with respect to
22 payments, gifts and other compensation to Health Care Professionals regarding OxyContin.

23 11. In the promotion and marketing of OxyContin, Purdue shall not misrepresent the
24 existence, non-existence, or findings of any medical or scientific evidence, including anecdotal
25 evidence, relating to Off-Label Uses of OxyContin. Purdue shall not provide any information
26 that is misleading or lacking in fair balance, as defined in 21.C.F.R. 202.1, as may be amended or

1 supplemented, or as appearing in FDA Guidances for Industry from time to time, in any
2 discussion of the Off-Label Uses of OxyContin.

3 12. Purdue shall not sponsor or fund any educational events where Purdue has
4 knowledge at the time the decision for sponsorship or funding is made that a speaker will
5 recommend the Off-Label Use of OxyContin. Further, Purdue shall not promote or fund Health
6 Care Professionals' attendance at educational events where Purdue has knowledge, at the time of
7 said promotion, that Off-Label Use of OxyContin will be recommended or encouraged.

8 13. Purdue shall, no later than thirty (30) business days after the Effective Date of this
9 Judgment, establish, implement and follow an OxyContin abuse and diversion detection program
10 consisting of internal procedures designed to identify potential abuse or diversion of OxyContin
11 in certain settings (the "OxyContin Abuse and Diversion Detection Program"). The OxyContin
12 Abuse and Diversion Detection Program will apply to Purdue employees and contract or third-
13 party sales representatives, including Medical Liaisons, who contact practicing Health Care
14 Professionals in person or by telephone for the purpose of promoting OxyContin. That Program
15 directs those persons to report to the Office of the General Counsel situations, including, but not
16 limited to the following examples, to the extent that such information or activities are observed
17 or learned of by them: a) an apparent pattern of an excessive number of patients for the practice
18 type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-
19 only capacity, or patient-prescriber interactions that are exceedingly brief or non-existent; b) an
20 atypical pattern of prescribing techniques or locations, such as repeated prescribing from an
21 automobile, or repeated prescribing at atypical times, such as after usual office hours when the
22 Health Care Professional is not on call; c) information from a highly credible source or several
23 sources (e.g., pharmacists, law enforcement, other health care workers) that a Health Care
24 Professional or their patients are abusing or diverting medications; d) sudden, unexplained
25 changes in prescribing or dispensing patterns that are not accounted for by changes in patient
26 numbers or practice type; e) a Health Care Professional who has a disproportionate number of

1 patients who pay for office visits and dispensed medications with cash; f) multiple allegations
2 that individuals from a particular practice have overdosed; or g) unauthorized individuals signing
3 prescriptions or dispensing controlled substances. Upon identification of potential abuse or
4 diversion involving a Health Care Professional with whom Purdue employees or its contract or
5 third-party sales representatives, including Medical Liaisons, interact, Purdue will conduct an
6 internal inquiry which will include but not be limited to a review of the Health Care
7 Professional's prescribing history, to the extent such history is available and relevant, and shall
8 take such further steps as may be appropriate based on the facts and circumstances, which may
9 include ceasing to promote Purdue products to the particular Health Care Professional, providing
10 further education to the Health Care Professional about appropriate use of opioids, or providing
11 notice of such potential abuse or diversion to appropriate medical, regulatory or law
12 enforcement authorities. Purdue's obligations under this Section shall expire ten (10) years
13 following the Effective Date of this Judgment or three months from the date on which the last of
14 Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall be
15 earlier than seven (7) years following the Effective Date of this Judgment.

16 14. Purdue shall implement and maintain a training and education program with
17 respect to the OxyContin Abuse and Diversion Detection Program, and shall require all Purdue
18 employees and contract or third-party sales representatives, including Medical Liaisons, who
19 contact practicing Health Care Professionals in person or by telephone for the purpose of
20 promoting OxyContin to complete the training and education program no later than thirty (30)
21 business days after the Effective Date of this Judgment. Further, Purdue shall require those
22 Purdue employees and contract or third-party sales representatives, including Medical Liaisons,
23 who contact practicing Health Care Professionals in person or by telephone for the purpose of
24 promoting OxyContin to complete the training and education program before being allowed to
25 market or promote OxyContin. Purdue's obligations under this Section shall expire ten (10)
26 years following the Effective Date of this Judgment or three months from the date on which the

1 last of Purdue's patents covering OxyContin expires, whichever is earlier, but in no event shall
2 be earlier than seven (7) years following the Effective Date of this Judgment.

3 15. Within 90 days of the Effective Date of this Judgment, Purdue shall provide to
4 each Health Care Professional whom Covered Persons contact, written, non-branded educational
5 information related to detecting and preventing abuse and diversion of opioid analgesics. To the
6 extent that Purdue concludes that a specific Health Care Professional needs repeated exposure to
7 such non-branded educational materials, Purdue will provide those materials. Purdue's
8 obligations under this Section will remain in effect for ten (10) years following the Effective
9 Date of this Judgment.

10 16. Purdue shall continue to review news media stories addressing the abuse or
11 diversion of OxyContin and undertake appropriate measures as reasonable under the
12 circumstances to address abuse and diversion so identified, including but not limited to, (i)
13 correcting misinformation, (ii) offering non-branded educational materials to local substance
14 abuse prevention and treatment initiatives, or (iii) directing Health Care Professionals to
15 Purdue's Medical Services group for fair and balanced information on appropriate use of opioid
16 analgesics, prevention and detection of abuse and diversion. Purdue's obligations under this
17 Section shall expire ten (10) years following the Effective Date of this Judgment or three months
18 from the date on which the last of Purdue's patents covering OxyContin expires, whichever is
19 earlier, but in no event shall be earlier than seven (7) years following the Effective Date of this
20 Judgment.

21 17. No sales incentive (bonus) program for sales of OxyContin shall allow incentive
22 credit to be earned for a Health Care Professional who has been identified through the
23 OxyContin Abuse and Diversion Detection Program as one upon whom sales representatives
24 shall not call. In addition, Purdue shall not employ a compensation structure for persons
25 involved in marketing or promoting OxyContin that is based exclusively on the volume of
26 OxyContin sales.

1 18. For a period of ten (10) years following the Effective Date of this Judgment,
2 Purdue's performance evaluation of persons involved in marketing or promoting OxyContin
3 shall meaningfully take into account that sales persons inform Health Care Professionals to
4 whom the sales persons promote OxyContin about its potential for abuse and diversion, and how
5 to minimize those risks; failure to do so shall be considered as a basis for disciplinary action,
6 including, but not limited to censure, probation and termination.

7 19. In its promotion and marketing of OxyContin, Purdue shall not misrepresent, in
8 any written or oral claim relating to OxyContin, that its sales, medical or research personnel have
9 experience or credentials or are engaging in research activities if they do not in fact possess such
10 credentials or experience, or are not engaging in such activities.

11 20. All material used in promoting OxyContin, regardless of format (audio, internet,
12 video, print) and whether directed primarily to patients or to Health Care Professionals, shall, not
13 inconsistent with the Package Insert, contain only information that is truthful, balanced,
14 accurately communicated, and not minimize the risk of abuse, addiction or physical dependence
15 associated with the use of OxyContin.

16 21. Purdue shall not provide samples of OxyContin to Health Care Professionals.

17 22. The obligations of Purdue under this Judgment shall be prospective only. No
18 Signatory Attorney General shall institute any proceeding or take any action against Purdue
19 under its State Consumer Protection Laws or any similar state authority, or under this Judgment,
20 based on Purdue's prior promotional or marketing practices for OxyContin.

21 23. Nothing in this Judgment shall require Purdue to:

- 22 (a) take an action that is prohibited by the FDCA, the Controlled Substances Act or
23 any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;
24 (b) fail to take an action that is required by the FDCA, the Controlled Substances Act
25 or any regulation promulgated thereunder, or by FDA or the Drug Enforcement Administration;
26 (c) refrain from dissemination of safety information concerning OxyContin; or

1 (d) refrain from making any written or oral promotional claim which is the same or
2 substantially the same as the language permitted by FDA under the OxyContin Package Insert
3 and which accurately portrays the data or other information referenced in the OxyContin
4 Package Insert.

5 24. Purdue shall:

6 (a) to the extent necessary for compliance with this Judgment, no later than ninety
7 (90) days after the Effective Date of this Judgment, institute compliance procedures which are
8 designed to begin training currently employed Covered Persons on the contents of this Judgment,
9 and about how to comply with this Judgment;

10 (b) submit to the Attorney General (per the Notice below), no later than one hundred
11 and twenty (120) days after the Effective Date of this Judgment, a written description of such
12 training;

13 (c) submit to the Attorney General (per the Notice below), one (1) year after the
14 Effective Date of this Judgment, a written affirmation setting forth Purdue's compliance with this
15 paragraph;

16 (d) for a period of three (3) years from the Effective Date of this Judgment, Purdue
17 shall advise in writing all Covered Persons of the requirements of Paragraphs 2 through 23 of
18 this Judgment;

19 (e) beginning one (1) year after the Effective Date of this Judgment, for a period of
20 three (3) years, produce and provide on an annual basis to the Attorney General on the
21 anniversary of the Effective Date of this Consent Judgment a report containing basic statistics on
22 Purdue's Abuse and Diversion Detection Program including, but not limited to, statistics on the
23 number of reports, the number of investigations, and a summary of the results, including the
24 number of "Do Not Call" determinations, but shall not include the names of any specific Health
25 Care Professionals; and

26

1 (f) upon written request, the Attorney General may obtain state-specific information
2 as described in subsection (e). In addition, Purdue agrees to accept service of a civil
3 investigative demand or similar process by the Attorney General requesting the names of any
4 specific Health Care Professionals described in subsection (e). The Attorney General in receipt
5 of such information shall not disclose it except as provided by law.

6 **III. PAYMENT TO THE STATES**

7 25. No later than thirty (30) days after the Effective Date of this Judgment, Purdue
8 shall pay nineteen million and five hundred thousand U.S. dollars (\$19,500,000.00), to be paid
9 by Purdue to the States by electronic fund transfer made payable to the Oregon Department of
10 Justice (as instructed by that Office) which shall divide and distribute these funds as designated
11 by and in the sole discretion of the Signatory Attorneys General as part of the consideration for
12 the termination of their respective investigations under the State Consumer Protection Laws
13 regarding the Subject Matter of this Judgment. Said payment shall be used by the States as and
14 for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to,
15 the consumer protection enforcement fund, including future consumer protection enforcement,
16 consumer education, litigation or local consumer aid fund or revolving fund, used to defray the
17 costs of the inquiry leading hereto, and may be used to fund or assist in funding programs
18 directed at combating prescription drug abuse, addiction and/or diversion, including, but not
19 limited to, education, outreach, prevention or monitoring programs, or for other uses permitted
20 by state law, at the sole discretion of each Signatory Attorney General.

21 **IV. GENERAL PROVISIONS**

22 26. This Judgment shall be governed by the laws of the state of Oregon.

23 27. This Judgment is entered into by the Parties as their own free and voluntary act
24 and with full knowledge and understanding of the nature of the proceedings and the obligations
25 and duties imposed by this Judgment.

1 28. Nothing in this Judgment constitutes any agreement by the Parties concerning the
2 characterization of the amounts paid pursuant to this Judgment for purposes of the Internal
3 Revenue Code or any state tax laws, or the resolution of any other matters.

4 29. This Judgment does not constitute an approval by the Attorney General of any of
5 Purdue's business practices, including its promotional or marketing practices, and Purdue shall
6 make no representation or claim to the contrary.

7 **V. REPRESENTATIONS AND WARRANTIES**

8 30. Purdue warrants and represents that it and its predecessors, successors and assigns
9 manufactured, sold and promoted OxyContin. Purdue further acknowledges that it is a proper
10 party to this Judgment. Purdue further warrants and represents that the individual(s) signing this
11 Judgment on behalf of Purdue is doing so in his (or her) official capacity and is fully authorized
12 by Purdue to enter into this Judgment and to legally bind Purdue to all of the terms and
13 conditions of the Judgment.

14 31. Each of the Parties represents and warrants that it negotiated the terms of this
15 Judgment in good faith.

16 32. The Signatory Attorney General warrants and represents that he is signing this
17 Judgment in his official capacity, and that he is fully authorized by his state to enter into this
18 Judgment, including but not limited to the authority to grant the release contained in Paragraphs
19 34 and 35 of this Judgment, and to legally bind the state to all of the terms and conditions of this
20 Judgment.

21 33. Purdue acknowledges and agrees that the Attorney General has relied on all of the
22 representations and warranties set forth in this Judgment and that, if any representation is proved
23 false, unfair, deceptive, misleading, or inaccurate in any material respect, the Attorney General
24 has the right to seek any relief or remedy afforded by law or equity in the state.

25 **VI. RELEASE**

26 34. Based on his or her inquiry into Purdue's promotion of OxyContin, the Attorney

1 General has concluded that this Judgment is the appropriate resolution of any alleged violations
2 of the State Consumer Protection Laws. The Attorney General acknowledges by his or her
3 execution hereof that this Judgment terminates their inquiry under the State Consumer Protection
4 Laws into Purdue's promotion of OxyContin prior to the Effective Date of this Judgment.

5 35. In consideration of the Compliance Provisions, payments, undertakings, and
6 acknowledgments provided for in this Judgment, and conditioned on Purdue's making full
7 payment of the amount specified in Paragraph 25, and subject to the limitations and exceptions
8 set forth in Paragraph 36, the State releases and forever discharges, to the fullest extent permitted
9 by law, Purdue and its past and present officers, directors, shareholders, employees, co-
10 promoters, affiliates, parents, subsidiaries, predecessors, assigns, and successors (collectively,
11 the "Releasees"), of and from any and all civil causes of action, claims, damages, costs,
12 attorney's fees, or penalties that the Attorney General could have asserted against the Releasees
13 under the State Consumer Protection Law by reason of any conduct that has occurred at any time
14 up to and including the Effective Date of this Judgment relating to or based upon the Subject
15 Matter of this Judgment ("Released Claims").

16 36. The Released Claims set forth in Paragraph 35 specifically do not include the
17 following claims:

- 18 (a) private rights of action by consumers, provided, however, that this Judgment
19 does not create or give rise to any such private right of action of any kind;
- 20 (b) claims relating to Best Price, Average Wholesale Price or Wholesale Acquisition
21 Cost reporting practices or Medicaid fraud or Abuse;
- 22 (c) claims of antitrust, environmental or tax liability;
- 23 (d) claims for property damage;
- 24 (e) claims to enforce the terms and conditions of this Judgment; and
- 25 (f) any state or federal criminal liability that any person or entity, including
26 Releasees, has or may have to the State.

1 **VII. NO ADMISSION OF LIABILITY**

2 37. This Judgment does not constitute an admission by Purdue for any purpose, of
3 any fact or of a violation of any state law, rule, or regulation, nor does this Judgment constitute
4 evidence of any liability, fault, or wrongdoing, by Purdue nor does Purdue's agreement in this
5 Judgment not to engage in certain conduct constitute an admission that Purdue has ever engaged
6 in such conduct. Purdue enters into this Judgment for the purpose of resolving the concerns of
7 the Attorney General regarding Purdue's promotional and marketing practices regarding
8 OxyContin. Purdue does not admit any violation of the State Consumer Protection Laws, and
9 does not admit any wrongdoing that could have been alleged by the Attorney General.

10 38. This Judgment shall not be construed or used as a waiver or any limitation of any
11 defense otherwise available to Purdue. This Judgment is made without trial or adjudication of
12 any issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including
13 this paragraph, shall be construed to limit or to restrict Purdue's right to use this Judgment to
14 assert and maintain the defenses of res judicata, collateral estoppel, payment, compromise and
15 settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or
16 future legal or administrative action or proceeding.

17 **VIII. DISPUTES REGARDING COMPLIANCE**

18 39. For the purposes of resolving disputes with respect to compliance with this
19 Judgment, should the Attorney General have legally sufficient cause (which shall include, at a
20 minimum, a reasonable basis to believe that Purdue has violated a provision of this Judgment) to
21 object to any promotional or marketing practices relating to OxyContin subsequent to the
22 Effective Date of this Judgment, then the Attorney General shall notify Purdue in writing of the
23 specific objection, identify with particularity the provisions of this Judgment and/or the State
24 Consumer Protection Laws that the practice appears to violate, and give Purdue thirty (30)
25 business days to respond to the notification; provided, however, that the Attorney General may
26

1 take any action upon notice to Purdue where the Attorney General concludes that, because of the
2 specific practice, a threat to the health or safety of the public requires immediate action.

3 40. Upon receipt of written notice and within the thirty (30) business-day period,
4 Purdue shall provide a good faith written response to the Attorney General's objection. The
5 response shall include an affidavit containing either:

6 a. A statement explaining why Purdue believes it is in compliance with the
7 Judgment; or

8 b. A detailed explanation of how the alleged violation[s] occurred; and

9 i. A statement that the alleged breach has been cured and how it has been
10 cured; or

11 ii. A statement that the alleged breach cannot be reasonably cured within
12 thirty (30) business days from receipt of the notice, but (1) Purdue has begun to take
13 corrective action to cure the alleged breach; (2) Purdue is pursuing such corrective action
14 with reasonable and due diligence; and (3) Purdue has provided the Attorney General
15 with a detailed and reasonable time table for curing the alleged breach.

16 41. Nothing herein shall prevent the Attorney General from agreeing in writing to
17 provide Purdue with additional time beyond the thirty (30) business-day period to respond to the
18 notice.

19 42. Nothing herein shall be construed to exonerate any failure to comply with any
20 provision of this Judgment after the date of entry or to compromise the authority of the Signatory
21 Attorney General to initiate a proceeding for failure to comply. Further, nothing in this
22 subsection shall be construed to limit the authority of the Signatory Attorney General to protect
23 the interests of the State.

24 43. The Signatory Attorney General represents that he or she will seek enforcement of
25 the provisions of this Judgment with due regard for fairness and, in so doing, shall take into
26 account efforts that Purdue has taken to cure any claimed violation of this Judgment.

1 44. Upon giving Purdue thirty (30) business days to respond to the notification
2 described in Paragraph 39 above, the Attorney General shall be permitted to request and Purdue
3 shall produce relevant, non-privileged, non-work-product records and documents in the
4 possession, custody or control of Purdue that relate to Purdue's compliance with each provision
5 of this Judgment as to which legally sufficient cause has been shown.

6 **IX. MODIFICATION OF CERTAIN OPERATIONAL PROVISIONS**

7 45. Any party to this Judgment may petition the Court for modification on thirty (30)
8 days' notice to all other parties to this Judgment. Purdue may petition for modification if it
9 believes that the facts and circumstances that led to the Attorney General's action against Purdue
10 have changed in any material respect. The parties by stipulation may agree to a modification of
11 this Judgment, which agreement shall be presented to this Court for consideration; provided that
12 the parties may jointly agree to a modification only by a written instrument signed by or on
13 behalf of both Purdue and the Attorney General. If Purdue wishes to seek a stipulation for a
14 modification from the State, it shall send a written request for agreement to such modification to
15 the Attorney General at least 30 days prior to filing a motion with the Court for such
16 modification. Within 30 days of receipt from Purdue of a written request for agreement to
17 modify, the Attorney General shall notify Purdue in writing if the Attorney General agrees to the
18 requested modification. The Attorney General shall not unreasonably withhold his/her consent
19 to the modification.

20 **X. PENALTIES FOR FAILURE TO COMPLY**

21 46. The State may assert any claim that Purdue has violated this Judgment in a
22 separate civil action to enforce this Judgment, or to seek any other relief afforded by law. In any
23 such action or proceeding, relevant evidence of conduct that occurred before the Effective Date
24 shall be admissible on any material issue, including alleged willfulness, intent, knowledge, or
25 breach, to the extent permitted by law. By this Paragraph, Purdue does not waive any
26

1 evidentiary objection or any other objection it may have as permitted by law to the admissibility
2 of any such evidence.

3 **XI. COMPLIANCE WITH ALL LAWS**

4 47. Except as expressly provided in this Judgment, nothing in this Judgment shall be
5 construed as:

6 (a) relieving Purdue of its obligation to comply with all state laws, regulations
7 or rules, or granting permission to engage in any acts or practices prohibited by such law,
8 regulation or rule; or

9 (b) limiting or expanding in any way any right the State may otherwise have to obtain
10 information, documents or testimony from Purdue pursuant to any state law, regulation or rule,
11 or any right Purdue may otherwise have to oppose any subpoena, civil investigative demand,
12 motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to
13 any such state law, regulation, or rule.

14 **XII. NOTICES**

15 48. Any notices required to be sent to the State or to Purdue by this Judgment shall be
16 sent by overnight United States mail. The documents shall be sent to the following addresses:

17 For the State:

18 David Hart
19 Assistant Attorney General
20 Oregon Department of Justice
1162 Court Street NE
Salem, Oregon 97391-4095

21 For Purdue:

22 Vice President, Associate General Counsel
23 Purdue Pharma L.P.
24 One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431

25 ///

26 ///

1 **XIII. MONEY AWARD SUMMARY**

2 **A. Judgment Creditor:** STATE OF OREGON, ex rel HARDY MYERS, Attorney General
3 for the STATE OF OREGON.

4 a. **Address of Judgment Creditor:** Oregon Department of Justice, 1162 Court
5 Street NE, Salem, OR 97301-4096.

6 b. **Judgment Creditor's Attorney:** David A. Hart OSB #00275, Assistant
7 Attorney General.

8 c. **Address of Judgment Creditor's Attorney:** Oregon Department of
9 Justice, 1162 Court Street NE, Salem, OR 97301-4096. Telephone: (503) 947-
10 4333.

11 **Judgment Debtor:** Purdue Pharma L.P.

12 d. **Address of Judgment Debtor:** One Stamford Forum, Stamford, CT 06901-
13 3431

14 e. **Date of Birth:** N/A

15 f. **Social Security Number:** N/A.

16 g. **Driver's License No./State of Issuance:** N/A

17 h. **Judgment Debtor's Attorney:** Sarah Crooks, OSB # 971512, Perkins Coie LLP,
18 1120 NW Couch, 10th Floor, Portland, OR 97209

19 **B. Other person(s) or public body entitled to a portion of payment:** The Signatory
20 Attorneys General (to be divided per agreement among the Attorneys General).

21 **C. Principal Amount of Judgment:** \$19,500,000.00

22 **D. Pre-judgment Interest:** None.

23 **E. Post-judgment Interest:** At the rate of 9% (nine percent) per annum thereof from the
24 date 30 days after entry of Judgment.

25 **F. Attorneys Fees:** NA.

26 **G. Restitution:** NA

1 IT IS SO ADJUDGED AND ORDERED:

2 DATED this 8 day of May, 2007.

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5 Senior CIRCUIT COURT JUDGE

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FOR PURDUE

Robin E. Abrams

Robin E. Abrams
Vice President, Associate General Counsel
Purdue Pharma L.P.
The Purdue Frederick Company
Purdue Pharma Inc.
Tel: 203-588-8477
Fax: 203-588-6204


Date: May 1, 2007

Sarah J. Crooks

Sarah J. Crooks
Perkins Coie LLP
1120 N.W. Couch Street - 10th Floor
Portland, OR 97209-4128
Tel: 503-727-2252
Fax: 503-346-2252
Oregon Bar No. 97151

Date: May 3, 2007

1 FOR THE STATE OREGON
2 HARDY MYERS

3  5/8/07

4 David Hart OSB # 00275
5 Assistant Attorney General
6 Oregon Department of Justice
7 Of Attorneys for Plaintiff
8 Financial Fraud/Consumer Protection Section
9 1162 court Street NE
10 Salem, OR 97301-4096
11 Phone: (503) 947-4333
12 Fax: (503) 378-5017
13 Email: david.hart@doj.state.or.us
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DEPARTMENT OF JUSTICE
STATE OF OREGON

IN THE MATTER OF
INSYS THERAPEUTICS, INC,
Respondent.

NOTICE OF UNLAWFUL TRADE
PRACTICES AND PROPOSED
RESOLUTION

TO: Insys Therapeutics, Inc
444 South Ellis Street
Chandler, AZ 85224

c/o David Angeli
Angeli Unger Law Group LLC
121 SW Morrison Street, Suite 400
Portland, OR 97204

This notice is to inform you the Oregon Attorney General is authorized to file a lawsuit against you 10 days after you receive this notice. The Attorney General is required by statute to give you this notice. See Oregon Revised Statute 646.632.

To avoid the filing of a lawsuit against you, you may deliver an Assurance of Voluntary Compliance [AVC] to the Financial Fraud Section of the Oregon Department of Justice within 10 days after you receive this notice.

An AVC must be in writing and state what actions you intend to take to resolve the violations described below. The AVC is not an admission of violation of law and is submitted to a Circuit Court for the State of Oregon for approval and filing.

The Attorney General must approve and accept an AVC before an AVC is submitted to the Circuit Court. Once filed with the court, any willful violation of the terms of an AVC is a contempt of court which may result in punitive or remedial sanctions including confinement and civil penalties of up to \$25,000 per violation.

1 This notice becomes a public record after 10 days have passed following your receipt of
2 this notice.

3 The Attorney General sent you this notice because there are concerns you violated the
4 Oregon Unlawful Trade Practices Act, ORS 646.605 through ORS 646.656, including but not
5 limited to the following alleged conduct:

- 6 1) Implicitly misrepresenting to patients that Subsys® should be used to treat migraine,
7 neck pain, back pain, and other off-label uses for which Subsys is neither safe nor
8 effective. This implicit misrepresentation occurred when you paid patients' insurance co-
9 payments even when you knew the prescription was off-label or contraindicated; when
10 you arranged for free Subsys to be provided to patients even when you knew the free
11 product was for an off-label or contraindicated use; and when you advocated to obtain
12 insurance payments to patients for Subsys when you knew Subsys was to be used for an
13 off-label or contraindicated use.
- 14 2) Implicitly misrepresenting to doctors that Subsys could be used to treat migraine, neck
15 pain, back pain, and other off-label uses for which Subsys is neither safe nor effective.
- 16 3) Implicitly misrepresenting that the doctor whom you paid to teach Oregon physicians
17 about Subsys was qualified to prescribe and teach about Subsys when in fact, he was not
18 qualified.
- 19 4) Misrepresenting that a paper written by a well-known doctor supported the definition of
20 break through cancer pain used by you to promote Subsys when in fact, the paper did not
21 support the definition.
- 22 5) Misrepresenting that Subsys should be used to treat mild breakthrough cancer pain when
23 in fact, the potential harm of using Subsys to treat mild pain far outweighs any possible
24 benefit.
- 25 6) Employing an unconscionable tactic by making payments to doctors that you intended to
26 be a kickback to incentivize the doctor to prescribe Subsys.

- 1 7) Employing an unconscionable tactic by targeting Subsys promotion at doctors whom you
2 knew, or should have known, misprescribed Schedule II opioid drugs such as Subsys.
- 3 8) Employing an unconscionable tactic by targeting doctors for Subsys promotion when you
4 knew, or should have known, that the doctor only prescribed Subsys for off-label uses for
5 which Subsys is neither safe nor effective.
- 6 9) Employing an unconscionable tactic by arranging for free Subsys to be provided to
7 patients, and paying patients insurance co-payments for off-label uses of Subsys that you
8 knew, or should have known, were neither safe nor effective.
- 9 10) Employing an unconscionable tactic by pressuring sales representative to solicit doctors
10 to shorten the label mandated titration schedule designed to protect patients.

11 **Background**

12 Starting in January, 2012, Insys Therapeutics, Inc. (Insys) promoted and sold in Oregon
13 the Schedule II opioid drug Subsys. Schedule II opioid drugs have a high potential for abuse and
14 addiction. They can also have serious side effects which include respiratory depression and
15 death.

16 Subsys consists of the powerful and highly addictive narcotic fentanyl administered
17 through a sub-lingual (under the tongue) spray. Because it is absorbed rapidly into the
18 bloodstream through the sub-lingual mucosa, Subsys has a rapid onset. Subsys is one of a class
19 of drugs described as Transmucosal Immediate-Release Fentanyl (“TIRF”).

20 To ensure that prescription drugs sold in the United States are safe and effective, the
21 Food Drug and Cosmetic Act (“FDCA”) requires drug manufacturers to submit a new drug
22 application (“NDA”) for all prescription drugs sold in the United States. The NDA must include
23 clinical trials sufficient to prove to the U.S. Food and Drug Administration’s (“FDA’s”)
24 satisfaction that the drug is safe and effective for each and every indication (use) for which the
25 drug is sold. If a manufacturer wants to market a drug for an indication not initially approved by
26 FDA, the company must submit a supplemental new drug application (“sNDA”) that

1 demonstrates to FDA's satisfaction that the drug is safe and effective for the new indication. The
2 Food Drug and Cosmetic Act ("DCA makes it unlawful for companies to promote drugs for
3 indications FDA has not approved. Since FDA regulates drug manufacturers and the promotion
4 of drugs, but not the practice of medicine, doctors are free to prescribe drugs for indications for
5 which FDA has not determined that the drug is safe and effective. Such prescribing is described
6 as "off-label," meaning outside the FDA-approved label.

7 Based on the Subsys NDA submitted by Insys, FDA determined that Subsys may only be
8 lawfully promoted "for management of breakthrough pain in cancer patients 18 years of age or
9 older who are already receiving and who are tolerant to opioid therapy for their underlying
10 persistent cancer pain."¹ Any other use would be off-label. FDA also determined that to ensure
11 appropriate usage, Subsys is only intended to be prescribed by "pain specialists who are
12 knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." The FDA-
13 approved label also expressly provides that Subsys is "contraindicated" (should never be used) to
14 treat migraine headaches.

15 Although not expressly contraindicated in the label, Subsys should also not be prescribed
16 to treat most musculoskeletal pain, such as fibromyalgia, neck pain, and back pain, for which
17 Subsys has not been shown to be safe or effective. In fact, prescribing of opioids for back and
18 neck pain is often harmful and may ultimately lead to increased pain, dysfunction, and disability.

19 To help protect against Subsys' potentially fatal side effects, and to reduce the risk of
20 misuse and abuse, FDA determined that doctors should use the lowest possible dose of Subsys
21 that adequately treats a patient's symptoms. This is achieved through "titration" where the
22 doctor initially prescribes 100 micrograms (unless the patient is already using another TIRF, in
23 which case the starting dose can be slightly higher) and slowly increases to higher dosages at a
24 specified schedule while waiting at each dose level to determine whether the patient's pain is
25 adequately managed. While the highest dose of Subsys is 1600 micrograms, according to studies

26 _____
¹ Subsys label.

1 included in the FDA approved label, breakthrough cancer pain is well managed in approximately
2 25% of patients at 400 micrograms or less. Although patients benefit from using the lowest
3 possible dose, Insys earns more money when a higher dose is prescribed, as do Insys sales
4 representatives whose compensation is based on commission.

5 The first TIRF drug approved by FDA was Actiq®, which has the same FDA approved
6 indications as Subsys. In 2008, Cephalon pleaded guilty to criminal and civil charges that it
7 promoted Actiq for off-label uses and targeted physician specialties such as Physical Medicine
8 and Rehabilitation doctors (“PM&R” or “Physiatrists”) who do not usually treat cancer patients
9 but commonly treat neck and back pain. Among other things, Cephalon admitted to promoting
10 Actiq off-label to treat migraine headaches.

11 As a result of the federal enforcement action against Cephalon, even before Subsys was
12 approved for sale, Insys knew that there was a problem with off-label use of TIRF drugs and that
13 prescribers of Actiq, and PM&R doctors in particular, had been targeted with off-label
14 messaging regarding TIRF drugs.

15 To reduce the risk of abuse, misuse, and diversion, FDA instituted a Risk Evaluation and
16 Management Strategy (“REMS”) for Subsys and other fentanyl products “to ensure that the
17 benefit of the drugs outweigh the risk of the drug.”² The purpose of this REMS was to educate
18 “prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and
19 overdose” for this class of drugs.³ Sadly, the REMS for fentanyl drugs is particularly necessary
20 in Oregon which in 2012 led the nation in the estimated rate of nonmedical use of prescription
21 opioids (6.4% versus the national mean of 4.6%).⁴

22 To address the opioid epidemic in Oregon, the Prescription Drug Taskforce, appointed by
23 previous Governor Kitzhaber to study the problem, specifically recommended that among other

24 _____
25 ² U.S.C. § 355-1.

26 ³ Press Release, *FDA Approves Shared system REMS for TIRF Products* (December 29, 2011), available at
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm285345.htm>.

⁴ Substance Abuse and Mental Health Services Administration, *The NSDUH Report: State Estimates of Nonmedical Use of Prescription Pain Relievers* (2012).

1 interventions, it is necessary to “educate prescribers and the public on the risks of opioid use and
2 to reduce the amount of opioids in circulation.”⁵

3 Unfortunately, rather than educate prescribers and the public about appropriate use of
4 Subsys in order to reduce the risk of abuse, misuse and diversion, Insys did the very opposite.
5 As alleged below, rather than promoting appropriate use of Subsys, Insys used unconscionable,
6 false, and deceptive sales tactics which had the potential of increasing the misuse of Subsys in
7 Oregon. When Insys began promoting Subsys in 2012, it consciously targeted prescribers of
8 Actiq already predisposed to prescribe TIRF drugs off-label, with unconscionable and deceptive
9 promotion of Subsys. Within two years of Subsys' release, it was reported that approximately
10 80% of Subsys prescriptions were for off-label uses.

11 **Insys Promoted Subsys Off- Label for Non-Cancer Pain such as Back Pain and Neck Pain,**
12 **Uses for which Subsys is Neither Safe Nor Effective**

13 As discussed above, Subsys was never approved by FDA to treat back pain, neck pain,
14 myalgia, migraine or any other non-cancer pain. Opioids in general are highly problematic for
15 non-cancer chronic pain⁶ and are often counter-productive for back pain.⁷ TIRFs in particular
16 are unsuited for treating these chronic conditions. Nonetheless, Insys promoted Subsys off-label
17 to treat a back and neck pain and other off-label pain conditions. Subsys did so by targeting
18 physicians who primarily treated the off-label pain but did not treat breakthrough cancer pain.
19 Insys' goal was to get the doctor to prescribe Subsys even though the nature of the doctor's
20 practice was to only treat non-cancer pain and use of Subsys could only be off-label.

21 Insys also worked with patients and doctors to get insurance to pay for Subsys for off-
22 label conditions for which it is neither safe nor effective; provided economic incentives to its

23 _____
24 ⁵Dennis McCarty et al., *Oregon's strategy to control prescription opioid misuse: a case study*, Journal of Substance
Abuse Treatment (2014), available at <http://dx.doi.org/10.1016/j.jsat.2014.07.012>.

25 ⁶Roger Chou et al., *The Effectiveness and Risks of Long-Term Opioid Therapy for Chronic Pain: A Systematic
Review for a National Institutes of Health Pathways to Prevention Workshop Effectiveness and Risks of Long-Term
Opioid Therapy for Chronic Pain*, 162 Ann Intern Med. 276 (2015).

26 ⁷Richard A. Deyo et al., *Opioids for low back pain*, 350 BMJ 6380(2015).

1 sales reps to promote Subsys off-label for non-cancer pain; implicitly encouraged sales
2 representatives to promote off-label for non-cancer; paid patient co-pays when Insys knew the
3 Subsys prescription was for an off-label or even a contraindicated use; and gave free samples to
4 patients when Insys knew that the drug was to be used off-label.

5 From the start, Insys made the strategic decision to target doctors who were already
6 prescribing Actiq and other TIRFs and had already been exposed to Cephalon's unlawful off-
7 label promotional campaign which was the subject of the federal criminal action. Only a
8 minority of these physicians are oncologists likely to prescribe Subsys for the on-label indication
9 of breakthrough cancer pain.

10 Rather than focus on oncologists, Insys targeted specialties like PM&R that rarely, if
11 ever, treat breakthrough cancer pain but commonly treat neck and back pain. A good example of
12 this was Insys' aggressive promotional campaign targeting Dr. Roy [REDACTED] a PM&R physician
13 practicing at [REDACTED] in Tigard, Oregon. As described below, Insys targeted
14 Dr. [REDACTED] even though Insys knew Dr. [REDACTED] does not treat patients with breakthrough cancer
15 pain and could not prescribe Subsys on-label.

16 On September 19, 2013, Insys hired Jonathan [REDACTED] Dr. [REDACTED]'s son, as its Oregon
17 Subsys sales representative. Jonathan [REDACTED] had no background in pharmaceutical sales or health
18 care. Shortly after he was hired, Jonathan set up a dinner meeting between his father, Insys
19 Regional Sales Director Beth McKey, and Stuart Rosenblum, an anesthesiologist with a long
20 history of speaking on behalf of pharmaceutical companies about drugs, including drugs that
21 were unlawfully promoted off-label to treat certain types of pain.⁸ Rosenblum is a long-time
22 acquaintance of Dr. [REDACTED]. The dinner took place October 21st, 2013 at Riccardo's Ristorante in
23 Lake Oswego; it cost about \$100 per person. Rosenblum was paid \$1,600 to speak to Dr. [REDACTED]
24 about Subsys at the dinner. Even before the dinner, Insys knew that Dr. [REDACTED] did not treat

25 ⁸ In 2009 Pharmacia & Upjohn Company pleaded guilty to a felony violation of the Food, Drug and Cosmetic Act
26 for misbranding Bextra with the intent to defraud or mislead. Although FDA rejected the Bextra NDA for an acute
pain indication, Pharmacia & Upjohn promoted it for this use anyway. Ultimately Bextra was totally withdrawn
from the market for any use. Dr. Rosenblum was one of Pharmacia's top Bextra speakers in Oregon.

1 patients with breakthrough cancer pain, and that the types of patients Dr. [REDACTED] treats would not
2 benefit from Subsys. In fact, Insys had been told repeatedly that this was the case. On
3 November 1, 2013 Jonathan [REDACTED] texted to his father:

4 "These people from my company are relentless and it's kind of pissing me off. I
5 have told them multiple times (starting with the interview) that you probably
6 won't be writing my product due to the type of practice you have, but my
7 manager just called me an[sic] told me that they were 'concerned' that I haven't
8 gotten you tirtf rems enrolled. I'm getting ready to tell them to **** off
9 [expletive deleted]. Now they told me that dr Kapoor⁹ contacted you. I need you
10 to help me to figure out what to say to them to calm them down."

11 When John [REDACTED] was asked during a sworn interview how many breakthrough cancer patients
12 were treated by his father at [REDACTED] he replied "None."

13 In addition to trying to use family relationships and old acquaintance to try to get Dr.
14 [REDACTED] to prescribe Subsys off-label, Insys also used flirtation. On October 27th, 2013 Dr. [REDACTED]
15 texted his son, asking if it "seemed weird" that he [Dr. [REDACTED]] was getting texts from Beth
16 McKey proposing "tequila dates." In a sworn interview Jonathan [REDACTED] was asked:

17 **Q What did you say in response to your father's question, "Does it seem
18 weird to you"?**

19 A Probably something along the lines of, She's a cougar and that's what she's
20 going to do.

21 **Q She is a cougar?**

22 A Yeah. In the general term of cougarism.

23 **Q So why was -- why -- just to continue with that, why was Beth sending
24 these texts to your father?**

25 A Yeah, I don't want to get down like a rabbit hole of speculation, but, you
26 know, she -- you know, attractive lady. She thought she could use that to kind of
27 sway doctors to write, and so she would send my dad text messages like that.

⁹ Kapoor is the founder of Insys and the Executive Director of the Insys Board of Directors and has been closely involved with the development of Subsys.

1 Insys also sought to influence Dr. [REDACTED] by offering to make him a Subsys promotional
2 speaker even though Dr. [REDACTED] had never prescribed Subsys and did not treat the type of patients
3 that would benefit from Subsys. On November 12th, 2013 Jon [REDACTED] wrote to Dr. [REDACTED] "This
4 company really want to make you a speaker. Apparently Kapoor had good things to say about
5 you. The VP of sales wants to come out and speak with you . . . I apologize for being pushy."

6 Insys knew that Dr. [REDACTED] did not treat cancer patients and could not prescribe Subsys
7 on-label for the FDA approved indication. Nonetheless, Insys aggressively and persistently
8 targeted Dr. [REDACTED] and other non-oncologist physicians in an attempt to increase prescribing of
9 Subsys for off-label uses for which it is neither safe nor effective. Ultimately Insys' campaign to
10 get Dr. [REDACTED] to prescribe Subsys off-label was unsuccessful: Dr. [REDACTED] wrote no prescriptions
11 for Subsys. On December 19th, 2013, after only three months working as a Subsys sales
12 representative, Jonathon [REDACTED] resigned.

13 While targeting doctors who could only prescribe Subsys off-label, Insys expected its
14 sales representatives to implicitly promote Subsys for off-label uses. Although lip service was
15 paid to not breaking the law, the expectation was that sales representatives would do just that.
16 Jaimi Hooker was Insys' first and longest serving Oregon Subsys sales representative. In a
17 sworn interview, she testified:

18
19 **Q This was for a diagnosis of back pain. Was there a discussion in the**
20 **monthly meeting about doctors writing prescriptions for SUBSYS for back**
pain?

21 A It would be, it would definitely be talked about. Like what are you seeing what
22 providers write for? Definitely back pain came up.

23 **Q Were you implicitly encouraged by your superiors to try to get docs to**
write for back pain?

24 A Yes. In like as on the label as you can kind of way, yes.

25 **Q So the goal was to try to get docs to write for back pain but still technically**
26 **not ask them to directly write for back pain?**

1 A Right. Or just like imply do you have any patients that experience breakthrough
2 cancer pain.

3 **Q It was marketing for off-label uses by implication, is that correct?**

4 A I would say that that's fair to say.

5 In another portion of the interview, Hooker indicated that Insys managers expected reps
6 to ask for all of a doctor's TIRF business – including off-label uses.

7 **Q This is another exchange involving Karen Hill and Richard Simon. If we
8 go to the second page of this document there is an email from December 14,
9 2012 from Rich to Karen. And again, they are talking about you and an
10 assessment of Jamie[sic], and they talk about you asking doctors to write to
11 their capabilities. What does it mean to have a doctor write to their
12 capability?**

13 A I think it means that they were probably writing for our competitors, our
14 competitor, so maybe it meant to get all of that business and also write more.
15 They probably felt like they had patients, like these providers had patients that
16 could be written that would be provided with SUBSYS.

17 **Q A few more lines down Rich says that "she, "meaning you, "is at the point
18 where her doctors truly like HER" -- cap HER -- to have the difficult
19 conversations and try to move them. What's the difficult conversation?**

20 A I think the difficult conversation was to ask them to write more.

21 **Q Why would that be difficult?**

22 A Because it would be asking them to take business from our competitors who
23 they probably have a relationship with like the other reps. But also it would
24 probably imply writing more off-label. I think that that's kind of what that means.
25 It's like trying to find patients.

26 Insys also pressured sales representative to circumvent the Subsys label, even parts of
the label relating to safety and titration. As already discussed, the Subsys label expressly
instructs prescribers to start at the lowest possible dose and titrate slowly upward in a way that
would allow for the doctor to determine the lowest possible effective dose. However, whenever
a doctor followed the label and started low, Insys sent an email to the doctor's sales
representative that was copied to top management which instructed the rep to "report back to

1 *your manager within 24 hours on WHY the low dose was used and HOW the doctor plans to*
2 *titrate the patient to effective dose.”* The clear implication of these communications was to
3 pressure the sales representative to try to get the doctor to prescribe a higher dose – even before
4 it had been determined whether the lower dose is effective.

5 Sales representatives also had an economic incentive for doctors to prescribe a high dose
6 and to prescribe Subsys off-label since Insys’ compensation plan paid sales representatives based
7 on the value of the prescriptions written by the sales representatives’ doctors and the price of
8 Subsys was based on the size of the dose. The higher the dose, the higher the price and the
9 higher the commission. Moreover, sales reps received their commission even when Insys knew
10 that the prescription was for an off-label or contraindicated use.

11 Insys often knew when a prescription was for an off-label or contraindicated use because
12 Insys provided reimbursement assistance to patients with insurance prior authorization requests.
13 For example, when sports medicine doctor Jimmy D. Huebert of the Sports and Spine Center in
14 Tualatin prescribed Subsys for a patient with a herniated disc, Insys filled out the prior
15 authorization form on behalf of the doctor and actively assisted in submitting the form. Insys did
16 the same when James Gallant (discussed further below) prescribed Subsys for a diagnosis of
17 “Back Pain,” and then again when Gallant prescribed Subsys for “neck pain.” Insys similarly
18 assisted with the prior authorization process for at least five off-label prescriptions written by
19 Stuart Rosenblum which list diagnoses of spinal stenosis, osteoarthritis, myalgia, myositis, post
20 laminectomy syndrome, neuralgia neuritis and radiculitis - but not for breakthrough cancer pain.
21 Insys also submitted reimbursement forms for at least five other Oregon patients with diagnoses
22 such as chronic pain syndrome. As discussed further below, Insys even went so far as to provide
23 pre-authorization assistance and reimbursement assistance when Insys knew that the prescription
24 was for a contraindicated use. Moreover, under the Insys Subsys “Patient Savings Program,”
25 these patients who Insys knew were prescribed Subsys for off-label uses were eligible to receive
26 up to 60 free units of Subsys. Insys also paid the patients’ out-of-pocket copay for up to \$500 for

1 each prescription. All told, out of 18 preauthorization forms submitted by Insys on behalf of
2 Oregon patients that are known to DOJ, 14 (78%) were for off-label uses related to chronic, non-
3 cancer pain such as chronic pain syndrome, joint pain involving multiple sites, and degeneration
4 of lumbar or lumbosacral intervertebral discs. Insys was fully aware that its reimbursement
5 assistance program was unconscionably assisting in the misuse of Subsys. Moreover, by
6 providing reimbursement assistance, Insys implicitly misrepresented to patients, payors, and
7 physicians, that Subsys was appropriate for these off-label uses.

8 **Insys Unconscionably Targeted Roy Blackburn, a Problem Doctor who Misprescribed**
9 **Opiates, With Aggressive Subsys Promotion and Facilitated His Prescribing of Subsys for**
10 **Contraindicated Uses.**

11 On November 7th, 2013, Dr. Roy Blackburn entered into an Interim Stipulated Order with
12 the Oregon Medical Board to cease prescribing of controlled substances for chronic pain patients
13 pending the completion of the Board's investigation into his ability to safely and competently
14 practice medicine. On June 3rd, 2014, the Oregon Medical Board issued a Complaint against Dr.
15 Roy Blackburn that describes gross or repeated acts of negligence; prescribing of controlled
16 substances without a legitimate medical purpose; and prescribing of controlled substances
17 without following accepted procedures for examination of patients. In July 2014, Blackburn
18 agreed to a stipulated order which, among other things, prohibited him from prescribing
19 Schedule II drugs, or from prescribing any drug for chronic pain to a patient for more than 30
20 days in a one year period. Blackburn is a physiatrist and not a pain specialist who would be
21 knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Blackburn
22 treats chronic non-cancer pain patients. Nonetheless, he was the target of aggressive Subsys
23 promotion during the time period described in the Board of Medicine Complaint. He was the
24 third most heavily detailed (visited) doctor by Subsys sales representatives in Oregon.

25 Blackburn and his office were visited by Insys sales representatives at least 80 times; on
26 at least 28 of those visits, the sales representative brought coffee and/or snacks. On October 23,
2012, Insys paid Dr. James Gallant \$2,400 to speak to Blackburn and one of his employees at a

1 catered lunch at Blackburn's office. At this lunch, Gallant promoted Subsys for among other
2 things, treatment of mild breakthrough cancer pain (discussed further below). On November 26,
3 2012, Insys paid Dr. Stuart Rosenblum \$1,600 to give the same promotional talk to Blackburn
4 and two other doctors at Marche, a French restaurant in Eugene. Insys knew, or should have
5 known, that Dr. Blackburn is not a pain specialist knowledgeable and skilled in the use of
6 schedule II opioids to treat cancer pain. In fact, Insys knew that Blackburn prescribed Subsys for
7 migraine, an expressly contraindicated use, and helped Blackburn obtain third party payment for
8 the contraindicated use.

9 On February 18th, 2013, Insys Prior Authorization Specialist Liz Gurrieri wrote
10 Blackburn's Subsys sales representative Jaimi Hooker "FYI . . . I received a duplicate opt in for
11 Dr Blackburn's pt [name redacted] for 600 mcg. He is requesting 240 units per month for
12 migraines. I do not think we can get it approved but we can try . . ." On February 6th, 2013,
13 Gurrieri wrote to Hooker (copied to, among others, Director of Sales Rich Simon and Vice
14 President of Sales Alec Burlakoff) that she had received the request. On March 28th, 2013
15 Hooker wrote to Blackburn, "Hi Dr B! I tried forwarding you an email about [name redacted]. I
16 just wanted to let you know that he is now reapproved for Subsys and our company called the
17 pharmacy and spoke with Aaron to run a dummy script and it went through!" In addition to
18 being unconscionable, the sum total of this conduct was to misrepresent to the patient and the
19 third party payor that Subsys is appropriate for the treatment of migraines.

20 **Insys Unconscionably Targeted James Gallant, A Problem Doctor who Misprescribed**
21 **Opiates, With Aggressive Subsys Promotion. Despite Gallant's Lack of Qualifications,**
22 **Insys Hired Gallant to Teach Other Doctors about Subsys. The Payments made to Gallant**
23 **and other Doctors were intended to be Kickbacks to Increase Prescribing of Subsys.**

24 Dr. James Gallant is a medical doctor who has never been board certified by any medical
25 specialty. Except for a four-day commercial continuing education program in Las Vegas, he
26 lacks post graduate training in pain management. In October 2014, based in part on Gallant's
misprescribing of opioids, the Oregon Medical Board suspended Gallant's license for 90 days,

1 formally reprimanded him, imposed a \$10,000 civil penalty, placed him on probation for 10
2 years, ordered him to complete an assessment and education or remediation plan, a course in
3 medical ethics, and a course in prescribing, and ordered him to refrain from treating chronic pain.
4 Gallant has a long history of receiving letters of concern and formal reprimands from the Board
5 of Medicine, and in 1997 he was formally reprimanded and his license was suspended after it was
6 determined that he had euthanized a patient. Gallant is not a pain specialist knowledgeable of
7 and skilled in the use of Schedule II opioids to treat cancer pain. Nonetheless, Insys hired
8 Gallant as its top Oregon consultant to train doctors about safe usage of Subsys.

9 Gallant was Insys' top Oregon Subsys consultant. He was paid up to \$2,400 to give short
10 promotional talks about Subsys. The amount Insys paid Gallant for his talks was 50% more than
11 the amount paid Stuart Rosenblum, the second most frequent Oregon Subsys speaker who is a
12 board certified anesthesiologist. Gallant was also a paid member of a Insys "Advisory Board and
13 was paid to attend speaker training programs, including \$2,500 to attend a speaker training
14 program in San Francisco that occurred after he stopped doing Subsys talks. In 2012 and 2013,
15 Gallant's office was visited by Insys sales representatives over 100 times, more than any other
16 doctor in Oregon. On at least seven occasions, the sales rep brought lunch or breakfast for the
17 office. Gallant was also repeatedly taken out for meals by Insys sales representatives.

18 Some of the talks paid for by Insys were shams that were essentially an excuse to make a
19 payment to Gallant to encourage increased prescribing of Subsys. On one occasion, Gallant was
20 paid \$2,400 plus expenses to speak to his own physician assistant over a meal at an expensive
21 restaurant. In sworn testimony, Subsys sales representative Jaimi Hooker testified that this sham
22 talk was expressly approved by Director of Sales Rich Simon, who knew the only attendee at the
23 talk was Gallant's assistant.

24 Such sham talks were not unique to Gallant. For example, Stuart Rosenblum was paid
25 \$1,600 to speak at what was essentially a social event and an opportunity for Rosenblum to
26 market his practice to other doctors. As Rosenblum wrote in an invitation to the event (that was

1 copied to Jaimi Hooker): *“you are invited to a social event this Friday at 1530 SE 7th (near*
2 *Hawthorne) Vie de Boehme. Phone 503-360-1233 at 8PM. We are having food and drinks*
3 *supplied by Jamie[sic] of Insys. Wives and girlfriends are invited. Scott’s band will be playing.*
4 *They start about 9pm. I hope to see you there.”*

5 In a subsequent email that Rosenblum wrote to his clinic staff: *“I have rescheduled our*
6 *dinner event. . . Our pain clinic staff and our wives are invited. Please feel free to invite any*
7 *referring physicians and we can use this for marketing as well. Dinner is sponsored by Insys and*
8 *I will give a brief informal presentation. Otherwise the evening will be for socializing and*
9 *networking. RSVP to Jamie [sic]. . .”*

10 Insys was well aware that payments made to Gallant and Rosenblum were not for bona
11 fide educational events but rather were an attempt to buy good will and an obligation to prescribe
12 Subsys.

13 Insys fully intended that its payments to Gallant and Rosenblum would cause the doctors
14 to write more Subsys prescriptions. For example, after Subsys sales executive Karen Hill did a
15 site visit to Oregon and accompanied sales representative Jaimi Hooker on visits to Drs Gallant
16 and Rosenblum, Hill wrote to Vice President of Sales Alex Burlakoff and CEO Michael Babich
17 *“I managed to meet her speakers and challenged each of them (we are paying these guys*
18 *[Gallant and Rosenblum] and not seeing a return on our investment.”*

19 In another email from District Sales Manager Crystal Skelton (who had responsibility for
20 Oregon) to Director of Sales Rich Simon, which was subsequently forwarded to a number of
21 other sales representatives (including Oregon Sales Representative Jaimi Hooker), Skelton wrote
22 that she had confronted one of her speakers for failing to write a sufficient number of Subsys
23 prescriptions. She further wrote that *“[h]is response was ‘thank you for telling me this. It is a*
24 *privilege to be a speaker and an advocate for you and if I’m not giving you a full return on*
25 *investment then I want you to hold me accountable.”*

26

1 In another e-mail Simon wrote that Gallant and Rosenblum “*are on a short string with*
2 *me.*” When asked under oath why Gallant was on a short string with Simon, Hooker testified
3 that “*he felt like Dr. Gallant could have been writing more prescriptions.*” When asked if “*the*
4 *problem [was] that the return on investment for payments to Dr. Gallant was low,*” Hooker
5 responded, “*I would say yes.*”

6 Gallant himself confirmed Hooker’s observation. In a sworn response to an
7 interrogatory, Gallant wrote: “*As a result of my prescribing numbers being considered too low*
8 *for the company, I was told that I would not be used as a speaker again.*”

9 Through its payments to Gallant and Rosenblum, Insys unconscionably sought to
10 increase prescriptions written for Subsys. Gallant was chosen as a speaker not because he was
11 qualified to speak to doctors about Subsys – he was not - but to incentivize him to prescribe
12 Subsys. Nonetheless, Insys deceptively held Gallant out as a qualified speaker and sought out
13 Oregon physicians to attend his talks. Although Gallant’s prescribing of Subsys failed to meet
14 Insys’ expectations, Gallant was the top prescriber of Subsys in Oregon. Out of the total of
15 \$511,000 worth of Subsys sold in Oregon, Gallant wrote prescriptions worth almost \$250,000,
16 including \$95,800 paid by the Public Employee Benefits Board (PEBB). In 2013, Gallant and
17 Rosenblum were responsible for approximately 80% of all Subsys prescriptions filled in Oregon.
18 For the years 2012 and 2013, Gallant, Rosenblum, and Blackburn were responsible for 78% of
19 all Oregon Subsys prescriptions.

20 **Insys Deceptively Misrepresented that Subsys Should Be Used to Treat Mild Pain**

21 The definition for breakthrough cancer pain (“BTCP”) was critical for Insys because it
22 determined the breadth of the only FDA approved use for which, under federal law, Subsys
23 could be lawfully promoted. The broader the definition of BTCP, the wider the potential market
24 for Subsys. To broaden the approved indication of BTCP, Insys defined BTCP to include mild
25 pain. However, Subsys should never be prescribed solely to treat mild pain because Subsys’ risks
26 far outweigh its benefits for this use. To achieve its goal of a broad definition of BTCP that

1 includes mild pain, Insys knowingly fabricated a false citation to a paper written by RK
2 Portenoy, a well-known researcher and clinician.

3 As early as January 2011, the Insys Board of Directors considered two possible
4 definitions for BTCP. The first definition came from the National Cancer Institute and defined
5 BTCP as “*intense increases in pain* that occur with rapid onset even when pain control
6 medication is being used.” (Emphasis added). The second definition considered was a
7 “transitory exacerbation, or flare, of *moderate-to-severe intensity* over persistent pain in patients
8 receiving chronic opioid medication” and cited to a paper by RK Portenoy which defined BTCP
9 as a “transitory increase in pain to *greater than moderate intensity* which occurred on a baseline
10 pain of moderate intensity or less (that is, to *an intensity of ‘severe’ or ‘excruciating’*). . .”¹⁰
11 (Emphasis added).

12 Insys considered these two definitions at consultant meetings prior to product launch and
13 chose to use the Portenoy definition. At the time of Subsys’ launch in March 2012, Subsys
14 promotional materials accurately cited the Portenoy definition. However, starting in June 2012,
15 began to falsely cite Portenoy to define BTCP as “a flare of mild–to-severe pain in patients with
16 otherwise stable persistent pain.” Despite the fact that Portenoy’s definition expressly excluded
17 mild and moderate pain and covered only severe or excruciating pain, Insys falsely cited
18 Portenoy to include mild pain. The clear implication of Insys’ deceptive citation to Portenoy was
19 that it was appropriate and acceptable for doctors to prescribe Insys to treat even mild
20 breakthrough pain. However, it is never appropriate and acceptable to prescribe Subsys to treat
21 mild breakthrough pain because the potential harm to patients far exceeds any potential benefit.
22 These harms include addiction, diversion, and death. Improper use of opioids to treat mild pain
23 can actually make pain worse, a condition known as opioid-induced hyperalgesia.

24 Insys trained its sales representatives to use the deceptive definition of BTCP and to
25 falsely cite Portenoy. Between June 2012 and September 2013, a deceptive Subsys Core Visual

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¹⁰ Portnoy, RK, et al, Breakthrough pain: definition, prevalence, and characteristics, 41 273-281).

1 Aid was used by Insys sales representative to detail Oregon health care professionals. Sales
2 representatives were expected to use the Core Visual Aid whenever they detailed Subsys to a
3 health care provider or a provider's office. Between June 2012 and September 2013, Subsys
4 sales representatives engaged in at least 830 such sales visits. Each time a sales representative
5 used the deceptive BTCP definition in an Oregon presentation is a separate and distinct violation
6 of the UTPA.

7 Between October 12th, 2012 and November 26th, 2013, the deceptive BTCP definition
8 was used in a slide that was presented at all Subsys promotional talks in Oregon. There were at
9 least at least 23 presentations by four different speakers during this time period. Each time the
10 slide was used is a separate and distinct violation of the UTPA.

11 ***

12 If the Attorney General files a lawsuit, the Attorney General will allege that among other
13 violations, this conduct violated the Oregon Unlawful Trade Practices Act, ORS 646.605 through
14 ORS 646.656 by:

15 1) Implicitly misrepresenting to patients that Subsys should be used to treat
16 migraine, neck pain, back pain and other off-label uses for which Subsys is neither safe nor
17 effective. This implicit misrepresentation occurred when you paid patients' insurance co-
18 payments even when you knew the prescription was off-label or contraindicated; when you
19 arranged for free Subsys to be provided to patients even when you knew the free product was for
20 an off-label or contraindicated use; and when you advocated to obtain insurance payments to
21 patients for Subsys when you knew Subsys was to be used for an off-label or contraindicated
22 use.

23 2) Implicitly misrepresenting to doctors that Subsys could be used to treat migraine,
24 neck pain, back pain, and other off-label uses for which Subsys is neither safe nor effective.

25

26

1 3) Implicitly misrepresenting that the doctor whom you paid to teach Oregon
2 physicians about Subsys was qualified to prescribe and teach about Subsys when in fact, he was
3 not qualified.

4 4) Misrepresenting that a paper written by a well-known doctor supported the
5 definition of break through cancer pain used by you to promote Subsys when in fact, the paper
6 did not support the definition.

7 5) Misrepresenting that Subsys should be used to treat mild breakthrough cancer
8 pain when in fact the potential harm of using Subsys to treat mild pain far outweighs any
9 possible benefit.

10 6) Employing an unconscionable tactic by making payments to doctors that you
11 intended to be a kickback to incentivize the doctor to prescribe Subsys.

12 7) Employing an unconscionable tactic by targeting Subsys promotion at doctors
13 who you knew, or should have known, misprescribed Schedule II opioid drugs such as Subsys.

14 8) Employing an unconscionable tactic by targeting doctors for Subsys promotion
15 when you knew, or should have known, that the doctor only prescribed Subsys for off-label uses
16 for which Subsys is neither safe nor effective.

17 9) Employing an unconscionable tactic by arranging for free Subsys to be provided
18 to patients, and paying patients insurance co-payments for off-label uses of Subsys that you
19 knew, or should have known, were neither safe nor effective.

20 10) Employing an unconscionable tactic by pressuring sales representative to solicit
21 doctors to shorten the label mandated titration schedule designed to protect patients.

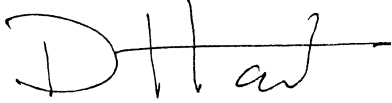
22 If the Attorney General files the lawsuit, the Attorney General will ask the court to order
23 you to pay:

- 24 1) Civil penalties of up to \$25,000 for each violation;
- 25 2) Restitution to anyone harmed by your acts; and
- 26 3) Our reasonable attorney's fees, costs and disbursements.

1 In addition, the Attorney General may ask the court to permanently enjoin you from
2 conducting any aspect of any trade or commerce in the State of Oregon.

3 Dated this 10th day of July, 2015.

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David A. Hart OSB #002750
Assistant Attorney-in-Charge
Health Fraud Unit/Consumer Protection Section
Oregon Department of Justice
1515 SW Fifth Ave, Suite 410
Portland, OR 97201
Phone: (971) 673-1880
Fax: (971) 673-1884
Email: david.hart@doj.state.or.us