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.

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

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

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

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

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

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

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

Background

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

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

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

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

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

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

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

[1] Subsys label.

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

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

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

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

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

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[2] U.S.C. § 355-1.

[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).

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interventions, it is necessary to "educate prescribers and the public on the risks of opioid use and to reduce the amount of opioids in circulation.[5]

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

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

As discussed above, Subsys was never approved by FDA to treat back pain, neck pain, myalgia, migraine or any other non-cancer pain. Opioids in general are highly problematic for non-cancer chronic pain[6] and are often counter-productive for back pain.[7] TIRFs in particular are unsuited for treating these chronic conditions. Nonetheless, Insys promoted Subsys off-label to treat a back and neck pain and other off-label pain conditions. Subsys did so by targeting physicians who primarily treated the off-label pain but did not treat breakthrough cancer pain. Insys' goal was to get the doctor to prescribe Subsys even though the nature of the doctor's practice was to only treat non-cancer pain and use of Subsys could only be off-label.

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

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[5] Dennis 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.

[6] Roger 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).

[7] Richard A. Deyo et al., *Opioids for low back pain*, 350 BMJ g6380(2015).

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

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

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

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

[8] In 2009 Pharmacia & Upjohn Company pleaded guilty to a felony violation of the Food, Drug and Cosmetic Act 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.

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

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

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

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

> Q **What did you say in response to your father's question, "Does it seem weird to you"?**
>
> A Probably something along the lines of, She's a cougar and that's what she's going to do.
>
> Q **She is a cougar?**
>
> A Yeah. In the general term of cougarism.
>
> Q **So why was - - why - - just to continue with that, why was Beth sending these texts to your father?**
>
> A Yeah, I don't want to get down like a rabbit hole of speculation, but, you know, she -- you know, attractive lady. She thought she could use that to kind of 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q Why would that be difficult?

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

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*

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

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

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

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

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

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

Blackburn and his office were visited by Insys sales representatives at least 80 times; on 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

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

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

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

Dr. James Gallant is a medical doctor who has never been board certified by any medical specialty. Except for a four-day commercial continuing education program in Las Vegas, he 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,

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formally reprimanded him, imposed a $10,000 civil penalty, placed him on probation for 10 years, ordered him to complete an assessment and education or remediation plan, a course in medical ethics, and a course in prescribing, and ordered him to refrain from treating chronic pain. Gallant has a long history of receiving letters of concern and formal reprimands from the Board of Medicine, and in1997 he was formally reprimanded and his license was suspended after it was determined that he had euthanized a patient. Gallant is not a pain specialist knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Nonetheless, Insys hired Gallant as its top Oregon consultant to train doctors about safe usage of Subsys.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Insys trained its sales representatives to use the deceptive definition of BTCP and to 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).

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

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

***

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

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

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

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

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

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

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

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

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

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

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

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

1) Civil penalties of up to $25,000 for each violation;

2) Restitution to anyone harmed by your acts; and

3) Our reasonable attorney's fees, costs and disbursements.

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

Dated this 10th day of July, 2015.

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

AUG - 5 2015

CIRCUIT COURT OF OREGON

COUNTY OF MULTNOMAH 15CV20593

IN THE MATTER OF: INSYS THERAPEUTICS, INC.	Case No. ASSURANCE OF VOLUNTARY COMPLIANCE

1.

This Assurance of Voluntary Compliance ("AVC") is an agreement between Insys Therapeutics, Inc. ("Insys" or "Respondent") and the Oregon Department of Justice ("ODOJ") acting pursuant to Oregon Revised Statute ("ORS") section 646.632.

PROCEDURE

2.

This AVC is a settlement of a disputed matter. It shall not be considered an admission of any violation of law, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Respondent expressly denies. This AVC does not constitute an admission or concession by Respondent for any purpose, of any fact or of a violation of any law, rule, or regulation, nor does this AVC constitute evidence of any liability, fault, or wrongdoing, all of which Respondent expressly denies. Respondent enters into this AVC for the sole purpose of resolving the concerns of ODOJ. Respondent does not admit any violation of any laws, including but not limited to the Oregon Unlawful Trade Practices Act, and does not admit any wrongdoing that could have been alleged by ODOJ. Respondent and ODOJ agree that no provision of the AVC operates as a penalty, forfeiture, or punishment under the Constitution of the United States, under the Constitution of the State of Oregon, or under any other provision of law.

3.

This AVC does not create a waiver or limit Respondent's legal rights, remedies, or defenses in any other action, and does not waive or limit Respondent's right to defend itself from, or make any argument in, any other matter, claim, or suit, including but not limited to any investigation or litigation relating to the subject matter or terms of this AVC. This AVC is made without trial or adjudication of any issue of fact or law or any finding of liability of any kind.

4.

This AVC shall be inadmissible in any case for any purpose, and shall not otherwise be used to support any claim, cause of action, right asserted or request for relief of any kind in any action against Respondent, except an action to enforce this AVC. This AVC shall not create a private cause of action or confer any right to any third party for violation of any federal or state statute or law except that ODOJ may file an action to enforce the terms of this AVC.

5.

This AVC settles and resolves ODOJ's investigation into the marketing and promotion of Subsys®, a sublingual fentanyl spray indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. For purposes of this AVC, the ODOJ investigation of Respondent's business practices as described in this paragraph shall be referred to as the "Matters Investigated."

6.

Respondent understands and agrees that this AVC is accepted by the ODOJ and it will be submitted to the Circuit Court of the State of Oregon for Multnomah County for approval, and, if approved, will be filed with the court pursuant to ORS 646.632(2).

7.

Respondent agrees to accept service of a conformed or court certified copy of this AVC by prepaid first class mail or via electronic mail sent to Respondent's attorney.

8.

If monies which are ordered to be paid in this AVC are not paid timely, ODOJ may convert the AVC to a money judgment under ORS 646.632(2); provided, however, ODOJ shall provide Respondent and Respondent's attorneys with written notice of any default in payment and Respondent shall have ten (10) days from the date of such notice to cure the default. In the event that such default is not cured, ODOJ may convert the AVC to a money judgment as provided herein. Respondent agrees that a copy of the money judgment may be sent to Respondent, via first class mail to the address following Respondent's signature and to Respondent's attorney.

9.

Respondent understands that, in addition to any other sanctions which may be imposed under the law, violation of any of the terms of this AVC may result in contempt of court proceedings, civil penalties of up to $25,000 for each violation, and such further relief as the court may deem appropriate. ORS 646.632(4), ORS 646.642(2) and ORS 646.636. If ODOJ believes that Respondent has failed to comply with any of the terms of this AVC, and if in ODOJ's sole discretion, failure to comply does not threaten the health or safety of the citizens of the State of Oregon, ODOJ shall notify Respondent in writing via electronic mail to fdelfosse@insysrx.com and overnight mail addressed to INSYS, 1333 S. Spectrum Blvd., Suite 100, Chandler, AZ 85286-8435, Attention: General Counsel, with a copy to Respondent's attorneys by electronic mail to john.bentivoglio@skadden.com and overnight mail addressed to Skadden, Arps, 1440 New York Ave NW, Washington D.C. 20005, Attention: John Bentivoglio, and any person subsequently designated by Respondent to receive such notice of failure to comply. The notice shall advise

Respondent of the manner in which it is believed that this AVC has been violated. Respondent shall then have fifteen (15) business days from the receipt of such written notice to provide a good faith written response to ODOJ's notice of noncompliance (the "Cure Period"). The response shall include an affidavit containing, at a minimum, either:

(A) a statement explaining why Respondent believes it is in compliance with the AVC; or

(B) an explanation of how the alleged violation occurred and

(1) a statement that the alleged breach has been cured and how; or

(2) a statement that the alleged breach cannot be reasonably cured within fifteen (15) business days from receipt of the notice, but:

(a) Respondent has begun to take corrective action to cure the alleged breach;

(b) Respondent is pursuing such corrective action with reasonableness and due diligence; and

(c) Respondent has provided ODOJ with a reasonable timetable for curing the alleged breach.

Nothing herein shall prevent ODOJ from agreeing in writing to provide Respondent with additional time beyond the fifteen (15) business day period to respond to the notice of failure to comply.

10.

The parties acknowledge that no other promises, representations, or agreements of any nature have been made or entered into by the parties. The parties further acknowledge that this AVC constitutes a single and entire agreement that is not severable or divisible, except that if any

provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect.

REMEDIES

11.

In the promotion and marketing of Subsys® in Oregon, Respondent shall not make any written or oral claim that is false, misleading, or deceptive.

12.

In the promotion and marketing of Subsys® in Oregon, Respondent shall not represent that Subsys® has approval, characteristics, uses, benefits or qualities that it does not have.

13.

In the promotion and marketing of Subsys® in Oregon, Respondent agrees to adhere to each of the following requirements:

A. Respondent shall not make any written or oral promotional claim for Subsys® that violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. or any regulation promulgated thereunder;

B. Respondent shall not make any written or oral promotional claim for Subsys® that violates any final written guidance documents issued by the Office of Prescription Drug Promotion.

C. Respondent shall not distribute any Subsys® that is adulterated or misbranded;

D. Respondent shall comply with all other applicable federal and state laws relating to the marketing and promotion of Subsys®, including but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and all accompanying regulations.

14.

In the promotion and marketing of Subsys® in Oregon, Respondent shall not promote Subsys® for treatment of mild breakthrough cancer pain or mild pain of any origin unless the FDA has expressly approved use of the word "mild" to describe the type of pain addressed in the promotion. The requirements of this AVC as stated in this paragraph shall expire on August 1, 2020.

15.

Respondent agrees to maintain and comply with written policies and procedures designed to ensure that the speaker program with respect to SUBSYS® implemented in Oregon:

A. Imposes a quarterly and annual cap on the number of speaker programs that can be conducted by a speaker;

B. Imposes an annual cap on payments that can be made to a speaker;

C. Requires pre-approval of all proposed program attendees;

D. Defines the objective criteria used to evaluate each speaker candidate's qualifications;

E. Imposes a cap on the number of programs an attendee can attend annually;

F. Conducts routine third-party monitoring of speaker programs;

G. Includes an annual third-party fair market value analysis of payment ranges for compensating health care providers in a consultant or speaking capacity;

H. Requires Respondent to make reasonable efforts to search readily accessible public information and to reject a speaker nominee or terminate an existing speaker relationship if such searches reveal that the speaker or nominee has been sanctioned by a state medical board or has been convicted of or pleaded guilty to violating any state or federal law.

If Respondent intends to make changes to any of the foregoing policies and procedures in connection with its Oregon speaker program, Respondent must provide written notification to ODOJ of the proposed changes 30 calendar days in advance of the proposed change. If Respondent does not receive a written objection within 30 calendar days of providing such notice, Respondent may implement the changes outlined in the notice. The requirements of this AVC as stated in this paragraph shall expire on August 1, 2020.

16.

In the promotion and marketing of Subsys® in Oregon, Respondent's sales representatives in Oregon shall not be assigned to detail family members about Subsys®. The requirements of this AVC as stated in this paragraph shall expire on August 1, 2020.

17.

In the promotion and marketing of Subsys® in Oregon, Respondent shall develop and comply with a written call plan for targeting Oregon physicians and other Oregon health care providers. Respondent's written policies and procedures shall require the call plan to be reviewed at least annually by a cross-functional team consisting of representatives from at least the Business Intelligence, Medical Affairs, Marketing, Regulatory, Legal and Compliance departments. This review will evaluate the bases upon which physician specialties or other health care providers are included or excluded from the call plans. If Respondent intends to make changes to the foregoing requirements in connection with its Oregon call plan, Respondent will provide written notification to ODOJ of the proposed changes at least 30 calendar days in advance of the changes taking effect. If Respondent does not receive a written objection within 30 calendar days of such notice, Respondent may implement the changes outlined in the notice. The requirements of this AVC as stated in this paragraph shall expire on August 1, 2020.

18.

Upon execution of this AVC, Respondent shall pay the sum of $533,000 to the State of Oregon to be allocated by the State of Oregon as follows:

A. $437,199 for deposit to the Department of Justice Account established pursuant to ORS 180.095 to be used by ODOJ as provided by law; and

B. $95,801 to the Public Employees Benefits Board.

19.

Within 90 days of the execution of this AVC, ODOJ shall identify non-profit or governmental organization(s) that work to prevent abuse, misuse, or misprescribing of opioid drugs in Oregon, or that provide services intended to remediate problems relating to misuse, abuse, or misprescribing of opioid drugs in Oregon. Within 30 days of the Attorney General identifying the organization(s), Respondent shall make a contribution to the organization(s) in the amount designated by ODOJ. Respondent shall not be required to contribute more than a total of five hundred and sixty-seven thousand dollars ($567,000). Respondent may not require any *quid pro quo* from the organization(s) that receives the contribution; provided, however that nothing in this AVC, including the foregoing *quid pro quo* prohibition is intended to (nor does it) prevent Respondent from classifying and characterizing payments hereunder as Respondent deems appropriate under applicable tax laws and regulations. The recipient of the contribution shall not be required to link or associate the service(s) paid for by the contribution with the Respondent.

20.

Respondent shall not represent or imply that ODOJ acquiesces in or approves of Insys's past business practices, current practices, efforts to reform its practices, or any future practices that Insys may adopt or consider adopting. ODOJ' s decision to settle this matter or to otherwise

unilaterally limit current or future enforcement action does not constitute approval or imply authorization for any past, present, or future business practice.

RELEASE

21.

In consideration of the remedies, payments and undertakings provided for in this AVC, and conditioned on Insys making full payment of the amount specified in Paragraph 18 and Paragraph 19, the State of Oregon releases and forever discharges, to the fullest extent permitted by law, Respondent and its past and present officers, directors, shareholders, employees, representatives, agents, affiliates, parents, direct and indirect subsidiaries, joint ventures, joint venturers, and the predecessors, attorneys, assigns, successors and transferees of any of the foregoing (collectively, the "Releasees"), from the following: all civil claims, causes of action, *parens patriae* claims, damages, restitution, fines, costs, fees, and/or penalties ("Released Claims") of any kind known or unknown, that were or could have been asserted against the Releasees through the date of this Release that arise from or relate to in any way the Matters Investigated and which are not expressly reserved or excluded.

22.

Notwithstanding any term of this Stipulated General Judgment, specifically reserved and excluded from the Released Claims as to any entity or person, including Releasees, are any and all of the following:

a. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Oregon;

b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Oregon, under any statute, regulation, or rule not expressly covered by the

release in paragraph 21 including, but not limited to, any and all of the following claims:

1. State or federal antitrust violations;
2. Medicaid violations, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to Oregon's Medicaid program;
3. State false claims violations.

c. Claims to enforce the terms and conditions of this AVC.

d. Any claims individual consumers have or may have under the State of Oregon's consumer protection laws against any person or entity, including Released Parties.

GENERAL PROVISIONS

23.

Nothing in this AVC shall require Insys to: (1) take an action that is prohibited by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, or any regulation promulgated thereunder, or by the U.S. Food and Drug Administration; or (2) fail to take action as required by the Federal Food, Drug, and Cosmetic Act, or any regulation promulgated thereunder, or by the U.S. Food and Drug Administration.

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24.

This AVC shall be effective (the "Effective Date") on the date that it is approved by the Multnomah County Circuit Court.

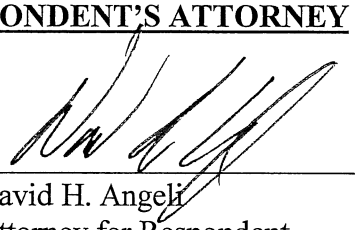
APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this _____ day of August, 2015.

_____
Circuit Court Judge

REVIEW BY RESPONDENT'S ATTORNEY

Approved as to form.



David H. Angeli
Attorney for Respondent

RESPONDENT'S SIGNATURE AND ACKNOWLEDGMENT

Respondent has read and understands this agreement and each of its terms. Respondent agrees to each and every term.

Corporate Respondent

I, Franc Del Fosse, being first duly sworn on oath depose and say that I am General Counsel of Insys Therapeutics, Inc. and am fully authorized and empowered to sign this Assurance of Voluntary Compliance on behalf of Respondent and bind the same to the terms thereof.

Franc Del Fosse
Print Name

General Counsel
Title

Address:
1333 South Spectrum Blvd., Ste. 100
Chandler, AZ 85286

SUBSCRIBED AND SWORN to me before this 31st day of July, 2015

Notary Public

DANA STANTON
Notary Public - Arizona
Maricopa County
My Comm. Expires Mar 21, 2018

ACCEPTANCE OF ODOJ

Accepted this 4th day of August, 2015.

ELLEN ROSENBLUM
Attorney General

David A. Hart OSB #00275
Assistant Attorney General
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