MIDDLESEX VICINAGE CIVIL DIVISION
P O BOX 2633
56 PATERSON STREET
NEW BRUNSWICK NJ 08903-2633

TRACK ASSIGNMENT NOTICE

COURT TELEPHONE NO. (732) 519-3728 COURT HOURS 8:30 AM - 4:30 PM

DATE: MARCH 28, 2017

RE: FULLER DEBORAH VS MATALON VIVIENNE

DOCKET: MID L -001859 17

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACK 3.

DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS FROM SERVICE ON THE FIRST DEFENDANT, WHICHEVER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED IS: HON ARNOLD L. NATALI

IF YOU HAVE ANY QUESTIONS, CONTACT TEAM 002 AT: (732) 519-3737 EXT 3737.

IF YOU BELIEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.

PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE WITH R.4:5A-2.

#### ATTENTION:

ATT: RICHARD J. HOLLAWELL
CONSOLE & HOLLAWELL PC
5 GREENTREE CENTER STE 117
525 RTE 73 NORTH
MARLTON NJ 08053

JUMGAR2

## Appendix XII-B1



## CIVIL CASE INFORMATION STATEMENT (CIS)

FOR USE BY CLE	ERK'S OFFICE ONLY
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ATTORNEY/PRO SE NAME Richard J. Hollawell				TELEPHONE NUMBER (856) 778-5500			COUNTY OF VENUE				
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OFFICE ADDRESS Five Greentree Centre, 525 Route 73 North,			, Suite ´	117, Marito	on, NJ 080	53	DOCUM Comp	ENT TYPE laint			
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## CIVIL CASE INFORMATION STATEMENT

(CIS)
Use for initial pleadings (not motions) under *Rule* 4:5-1

<b>CONTRACT</b>				
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CONSOLE & HOLLAWELL, P.C. Richard J. Hollawell, Esquire Attorney I.D. No.: 018122001 Mark C. Dewland, Esquire Attorney I.D. No.:023871986 Five Greentree Centre 525 Route 73 North, Suite 117 Marlton, New Jersey 08053 (856) 778-5500

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Attorney for Plaintiff, Deborah Fuller & David Fuller as Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller & David Fuller, Individually

DEBORAH FULLER & DAVID FULLER, as Administrators Ad Prosequendum for the Estate of SARAH A. FULLER, deceased and, DEBORAH FULLER, & DAVID FULLER, Individually

SUPERIOR COURT OF NEW JERSEY LAW DIVISION

MIDDLESEX COUNTY

DOCKET NO.: 2/859-17

ц(s) : : Civil Action

Plaintiff(s)

v.

VIVIENNE MATALON, M.D., TLC: HEALTHCARE 2, LLC, INSYS: THERAPEUTICS, INC., LINDEN CARE, LLC INC., JOHN DOE, 1-10 (fictitious), ABC CORPORATION 1-10 (fictitious), Individually, Jointly, Severally and/or in the Alternative

Defendant(s):

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, Deborah Fuller & David Fuller, as Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually, who currently reside at 47 West Temple Avenue, Stratford, New Jersey, 08084, by way of complaint against Defendants states as follows:

#### JURISDICTION AND VENUE

The Court is the proper Court of Jurisdiction and Venue. All actions herein occurred in New Jersey and the corporate defendants routinely conduct business in Middlesex County, New Jersey giving rise to proper venue.

#### **PARTIES**

- 1. Plaintiffs, Deborah Fuller & David Fuller, are the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, who are pursuing claims on behalf of the estate as well as individually. A true and correct copy of the Letters of Administration is attached as Exhibit "A".
- Decedent, Sarah A. Fuller, who was Deborah Fuller & David Fuller's daughter, resided at
   47 West Temple Avenue, Stratford, New Jersey.
- Decedent, Sarah A. Fuller, was born on November 30, 1983 and passed away on March 25,
   2016 as a result of an adverse reaction to prescription drugs, fentanyl (Subsys) and alprazolam.
- 4. Defendant, Vivienne Matalon, M.D. ("Dr. Matalon"), is a physician licensed in New Jersey under number 25MA05359600 who had been practicing in the field of internal medicine, at her former medical practice, TLC Healthcare 2 LLC operating as TLC Healthcare, located at 2070 Springdale Road, Cherry Hill, NJ 08034. Dr. Matalon's license to practice medicine in New Jersey was suspended on October 21, 2016 indefinitely pending further proceedings as a result of her treatment and reckless prescribing of numerous powerful and lethal opioid medications to Decedent, Sarah A. Fuller as more fully set forth in the Complaint.
- 5. At all relevant times hereto, Dr. Matalon was engaged in the practice of medicine as an internist and more specifically the practice of pain management, of which she was not board certified, utilizing opioid/opiate medications for pain, and was obliged to bring to bear in the practice of her profession and that of pain management the professional skill, knowledge and care in accordance with reasonably safe and accepted standards of care within the medical community.
- 6. Defendant, TLC Healthcare 2, LLC. ("TLC"), is a New Jersey corporate/business entity that at all times relevant hereto was providing health care services for profit in the State of New Jersey which regularly engages in the practice of medicine and through its agents, principals,

- servants and employees, is obliged to bring to bear the professional skill, knowledge and care required to practice pursuant to safe and accepted standards of medicine.
- 7. It is believed and averred that Dr. Matalon is a majority shareholder in and principal of TLC Healthcare 2, LLC and was acting as its agent or directly for herself and the corporation while providing health care services to decedent.
- 8. Plaintiffs are pursuing professional liability and other claims set forth against Dr. Matalon individually and as the Administrators Ad Prosequendum for the Estate of Sarah Fuller. A true and correct copy of Plaintiffs' Affidavit of Merit as to Dr. Matalon is attached as Exhibit "B".
- 9. Defendant, Insys Therapeutics, Inc., ("Insys"), is a Delaware Corporation with its principal place of business and executive offices located at 444 South Ellis Street, Chandler Arizona 85244. Insys is a pharmaceutical company that manufactures a prescription sublingual fentanyl spray with the brand name Subsys which is marketed, distributed, prescribed, sold, dispensed, administered and consumed throughout the United States, including New Jersey. At all times material hereto, Defendant Insys was acting individually and/or through its agents, servants or employees.
- 10. Defendant, Linden Care, LLC, ("Linden Care"), is a corporation/ business entity licensed as an out of state pharmacy in New Jersey under license number 28RO00043100 to dispense prescription drugs in the state of New Jersey. Linden Care's principal place of business and corporate headquarters is located at 130 Crossways Park Drive, Suite 101, Woodbury, N.Y. At all times material hereto, Defendant Linden Care was acting individually and/or through its agents, servants or employees.
- 11. Linden Care is a "concierge pharmacy service" specializing in filling, dispensing and shipping pain medications throughout the country via mail/commercial shipping services and Linden Care served as the, or one of the, exclusive pharmacy dispensers of Subsys for Defendant, Insys. Linden Care does not operate any physical retail pharmacies in New Jersey

- and its main method of dispensing and shipping Subsys throughout the country and in New Jersey was via Federal Express.
- 12. At all times relevant hereto Defendant, Linden Care, was engaged in the practice of Pharmacology, by and through its agents and employees who are obliged to bring to bear in the practice of their profession the professional skill, knowledge and care which they possessed and to pursue their profession in accordance with reasonably safe and accepted standards of Pharmacology. As deemed a healthcare provider pursuant to New Jersey law, Plaintiffs are pursuing professional liability and other claims set forth against Linden Care individually and as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller. A true and correct copy of Plaintiffs' Affidavit of Merit at to Linden Care is attached as Exhibit "C".

#### **FACTUAL CHRONOLOGY**

- 13. Subsys is Transmucosal Immediate-Release Fentanyl ("TIRF") and a Schedule II narcotic under the Controlled Substances Act, which is an extremely dangerous, addictive, and lethal synthetic opioid that is one hundred (100) times more powerful than morphine that was approved in 2012 by the FDA *only for* "the management of breakthrough pain in patients with cancer, 18 years or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain.
- 14. Subsys is a liquid formation of Fentanyl to be applied under the tongue, also called a sublingual spray. Subsys is among the most potent opioids available for human use. Its effects, while practically indistinguishable from heroin or morphine, have a greater potency and a shorter duration of action. Subsys is rapidly distributed to the brain, heart, lungs, kidneys and spleen.
- 15. Subsys, as a TIRF drug, was restricted by and subject to the FDA's Transmucosal Immediate-Release Fentanyl Risk Evaluation and Mitigation Strategy program ("TIRF-REMS") in order to ensure that the benefits of the drug outweighed the enormous risks

- associated with the drug, including but not limited to misuse, abuse, addiction and overdose. Consequently, the FDA required Defendant Insys to submit, and ultimately implement, a REMS strategy for Subsys called the TIRF-REMS access program.
- 16. Prescribers and pharmacists/dispensers of Subsys must comply with the TIRF-REMS requirements. Under the requirements, the prescriber and dispenser must review the education materials regarding Subsys, pass a knowledge assessment and then certify that he/she understands, *inter alia*, that Subsys is *only indicated for* "the management of breakthrough pain in patients with cancer, 18 years or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain, that the initial dosage shall be one hundred (100) micrograms, and any subsequent increase in dosage shall only be in one hundred (100) microgram increments.
- 17. As more fully discussed herein, Defendants, Insys and Linden Care have subverted, manipulated and violated the TIRF-REMS requirements in order to get the medical community to prescribe Subsys for a wide range of conditions for which Subsys was inappropriate, highly dangerous, contradicted and specifically forbidden by the FDA for Insys' financial benefit as the manufacturer and Linden Care's financial benefit as the dispenser. They have done this in Sarah Fuller's case and have done so regularly and systematically across the country.
- 18. As part of the TIRF-REMS program, healthcare professionals who engaged in prescribing Subsys were required to submit a Patient-Prescriber Agreement Form attesting that Subsys was only being prescribed for "the management of breakthrough pain in patients with cancer, who were already receiving and who were already tolerant to, around the clock opioid therapy for their underlying persistent cancer pain" and that this specific indication was fully disclosed to the patient before initiating and prescriptions for Subsys.
- 19. Since the approval of Subsys in 2012, Insys has engaged in a wide-ranging, systematic, intentional, deceptive and reckless pattern and practice of marketing, promoting and selling

- Subsys for *inter alia*, the treatment of pain of patients with a wide range of conditions for which Subsys was inappropriate, highly dangerous, contradicted, deadly and specifically forbidden by the FDA as further set forth herein.
- 20. It is not uncommon in the medical community for drugs to be prescribed for off-label purposes; however, drug manufacturers are not legally permitted to encourage or promote the use of regulated drugs for any indications that have not been formally approved by the FDA.
- 21. Insys blatantly disregarded this basic requirement as a drug manufacturer and systematically planned and successfully executed its unlawful, false, deceptive and reckless pattern and practice of marketing, promoting and selling Subsys for the treatment of pain of patients with a wide range of conditions for which Subsys was inappropriate, highly dangerous, contradicted and deadly. Plainly, Insys infiltrated the medical community with lies, misinformation, kickbacks and financial rewards which led to a large span of the medical community to prescribe Subsys for off-label indications for which there was no proven safe use.
- 22. Subsys is a very expensive drug for which there was great financial benefit for Subsys to be marketed, promoted, prescribed and dispensed on a more extensive basis than for a limited population of patients suffering breakthrough pain from malignant cancer. In this particular case, Sarah Fuller was a recipient of Medicare and Medicare was being billed as much as \$24,405.37 per month for the Subsys prescriptions being provided to Ms. Fuller over a fourteen (14) month period until she died.
- 23. In 2012, the first year Subsys was on the market, 4,528 prescriptions were written for Subsys resulting in sales of \$14 million and by the end of 2015 this exploded to 49,063 prescriptions written and sales of \$426 million, a 3200% increase. By the end of 2014, Subsys had gained a 40.2% share of the TIRF market and was the most prescribed brand name TIRF drug on the market. By the end of 2015, over 80% of prescriptions for Subsys were written for off-

- label unapproved indications, persons that were not suffering from cancer and breakthrough pain that was a result of cancer.
- 24. Insys achieved rapid growth through a multitude of false, fraudulent and misleading tactics. The Defendant Insys, at all times relevant hereto, employed sales representatives who were instructed to, and did, target medical prescribers who they knew treated few, if any, cancer patients and were instructed to, and did, specifically market the product for "breakthrough pain" instead of "breakthrough cancer pain" and other conditions for which the drug was not approved, indicated, safe or appropriate.
- 25. Throughout its various market territories, Insys would obtain the prescribing records of primary care physicians, pain management physicians and other practitioners outside of oncology to see who was prescribing opiates for general chronic pain and then send its sales representatives to those doctors' offices to urge them, and at many times pay them kickbacks, to prescribe Subsys off-label for unapproved non-cancer general pain.
- 26. As part of its campaign of spreading false and misleading information throughout the medical community about indications for which Subsys could be safely prescribed and while also misrepresenting the true dangers of the potent drugs, Insys developed its "Speakers Program" where management and sales personnel would recruit and pay physicians to hold seminars and spread its false and misleading information in order to lure unsuspecting physicians into prescribing Subsys for general pain that was not due to malignant cancer.
- 27. In addition to targeting prescribers, Insys specifically instructed its sales representatives to aggressively target individual patients who were taking opioid pain medication and convince them to switch to Subsys, regardless of whether the patient had breakthrough cancer pain and regardless of whether doing so would put the health of the patient at risk.
- 28. The FDA and the TIRF-REMS program required that Subsys should be used at the lowest possible dose to treat a patient's breakthrough cancer pain. Thus, when being prescribed for patients with breakthrough cancer pain, its only approved and indicated usage, Subsys was

- to be commenced at 100 micrograms ("mcg") and only safely increased or "titrated" slowly and in 100 mcg increments, but only if necessary.
- 29. Insys earns more money when a higher dose is prescribed, as do Insys sales representatives, whose compensation is based largely on commission. Subsys sales representatives are given an economic incentive to recommend a higher dose that is contrary to the FDA guidelines and the terms of the TIRF-REMS program.
- 30. Insys intentionally encouraged and mandated its sales representatives to recommend and encourage prescribers to skip titration and prescribe a higher dose of Subsys by representing to prescribers and patients the "effective dose" to be between 600 mcg and 1600 mcg, instead of the lowest possible dose to manage the patient's pain, contrary to FDA guidelines and the mandated TIRF-REMS access program agreement/contract.
- 31. Insys based commissions for its sales representatives on the overall dollar sale amount and not per unit, pushing its sales force to fall in line with its scheme of promoting and having Subsys prescribed for off-label indications at extremely dangerous dosages, knowing this would amount to a much broader market for Subsys as well as higher profits for the company while ignoring the obvious risk posed to patients, including the Decedent, Sarah A. Fuller.
- 32. In furtherance of its unlawful, intentional and reckless scheme in promoting and marketing Subsys for unapproved and indications for which it was never deemed safe, Insys set up an entire department at its corporate headquarters to defraud insurers by obtaining approval and ultimate payment for Subsys that had been unlawfully prescribed for indications for which there was no approval and safe and effective treatment. This department was known as the "Insys Reimbursement Center", ("IRC") where the sole function was to gain pre-approval and ultimate payment from insurers for Subsys being prescribed for indications for which it was not approved.
- 33. Insys defrauded insurers by disguising the identity and location of the IRC with the guise that the unit was actually from the prescribing doctor's office, providing false information about

- patients' true diagnoses, the type of pain being treated and the patients' previous course of treatment with other opiates that had failed. In addition, the IRC would block the phone numbers they were calling from and fraudulently and misleadingly inform insurers and pharmacy benefit managers that they were calling from the office of the practitioner.
- 34. Insys provided doctors with Insys generated Prior Authorization forms which Insys would partially pre-populate with information and the prescribing doctor would then complete with patient specific information with the Prior Authorization form then going back to the IRC where the staff would do whatever it needed to secure pre-approval and payment for Subsys for unapproved indications.
- 35. If Insys' IRC unit was unable to gain approval upon its first submission of the Prior Authorization for Subsys, Insys would then provide prospective patients with free product samples with the goal to get the patient dependent/addicted to Subsys so that Insys' IRC could later submit for approval and payment citing the patient's usage of Subsys.
- 36. Insys was successful with its unlawful, false, deceptive and reckless scheme and pattern of marketing and promoting Subsys for unapproved off-label purposes and in deceiving the medical community to prescribe Subsys for unapproved medical conditions; however, Insys needed a pharmacy to turn a blind eye to what it was doing and dispense Subsys throughout the country and Insys' main partner to execute its scheme during the years 2012-2016 was Linden Care, LLC.
- 37. As previously stated, Defendant, Linden Care, was subject to all of the terms and conditions of the TIRF-REMS access program and also certified that it knew it could only fill and dispense prescriptions for Subsys for the drug's only approved purpose, patients experiencing breakthrough pain due to malignant cancer.
- 38. Linden Care also certified that it would comply with the FDA dosage instructions in that patients for whom Subsys was properly indicated would be started on a 100 mcg initial dosage and increase in dosage would then be in 100 mcg increments.

- 39. According to the Controlled Substances Act and New Jersey Regulations pertaining to dispensing of controlled substances, Linden Care knew that it could not dispense Subsys or any controlled substance without physical possession of an original prescription.
- 40. At all times relevant hereto, Linden Care ignored and subverted the terms and conditions of the TIRF-REMS access program, by dispensing Subsys when it knew or should have known that Sarah Fuller, did not have pain from cancer, by accepting facsimile prescriptions and dispensing Subsys upon facsimile, by knowingly dispensing an initial prescription of Subsys for Decedent at 200 mcg and then within thirty (30) days dispensing Subsys for Decedent at 600 mcg, triple the initial prescription.
- 41. Despite Insys' systematic scheme and fraud as explained, as well as that of Defendant, Linden Care, Defendant, Dr. Matalon, in her own right, recklessly, wantonly and negligently disregarded her duty of care owed to her patient, Sarah Fuller by prescribing her dangerous amounts and combinations of schedule II and schedule IV narcotics, along with Subsys, without any medical justification which caused Sarah to become addicted which then led slowly and painfully to her death.
- 42. Decedent, Sarah Fuller first became a patient of Dr. Matalon and her medical practice TLC Healthcare on or about August 13, 2014. The purpose of Sarah seeking a doctor/patient relationship with Dr. Matalon was for Dr. Matalon to manage the various prescription medications that Sarah was taking for her various health conditions, i.e. fibromyalgia, back pain, with the goal to reduce and limit the need for the number of medications while managing her overall heath. However, Sarah Fuller did not have cancer nor pain from cancer.
- 43. At this initial consultation with Dr. Matalon, Sarah was accompanied by her parents, Deborah and David Fuller who had explicitly explained to Dr. Matalon that Sarah had been prescribed narcotic pain medications in the past and had become dependent/addicted and that Sarah had now overcome that and that narcotic pain medications were not to be part of any treatment regimen. Sarah was not taking any narcotic pain medication at the time she became

- a patient of Dr. Matalon on August 13, 2014.
- 44. Despite having been advised of Sarah's prior dependency on narcotic pain medication, on October 6, 2014, Dr. Matalon began prescribing narcotic pain medication to Sarah beginning with prescriptions for Oxycodone 7.5 mg every 6 hours and Oxycontin 10 mg every 12 hours.
- 45. At no time did Dr. Matalon ever attempt to develop any alternative treatment plan for Sarah that did not involve the use of narcotics or make any referrals to any specialists to develop a treatment plan to treat Sarah without the use of narcotic pain medication. From October 6, 2014 through January of 2015, without any medical explanation and justification, Dr. Matalon prescribed Sarah over three hundred (300) Oxycontin and 250 Percocet pills.
- 46. On or about January 5, 2015, at a follow up office visit in her office, Dr. Matalon orchestrated a "meeting" with Sarah, Sarah's father David, Melina Ebu-Issak, a sales representative employed by Insys and herself for the purpose of convincing Sarah that Subsys would be beneficial to her for the treatment of her neck and back pain. At that time, multiple material misrepresentations were made to Sarah and her father regarding the safe and legitimate use of Subsys as well misrepresentations as to the true and serious risks associated with the drug. Neither the Insys sales representative nor Dr. Matalon informed Sarah or her father that Subsys was fentanyl and that it was only approved and indicated for patients that were experiencing breakthrough cancer pain from malignant cancer.
- 47. At this January 5, 2015 "meeting" in Dr. Matalon's office, Insys succeeded with its unlawful and dangerous promotion of Subsys and Dr. Matalon recklessly acquiesced and Sarah was prescribed 200 mcg of Subsys to be sprayed under her tongue every four (4) hours. This prescription was in addition to the Percocet 7.5 mg and Oxycontin 10 mg she was already being prescribed by Dr. Matalon.
- 48. Upon this January 5, 2015 visit, Dr. Matalon, as instructed by the Insys sales representative, faxed the Subsys prescription to Linden Care and Linden Care intentionally and recklessly

- disregarded the law and the TIRF-REMS requirements by then dispensing a large carton of the 200 mcg Subsys which it had delivered via Federal Express to Sarah's doorstep.
- 49. Twenty days later, on January 26, 2015, without any explanation and medical justification, upon the urging of the Insys sales representative and in violation of the TIRF-REMS program and agreement, Sarah's Subsys prescription was tripled in strength to 600 mcg., to be taken along with the aforementioned daily doses of Percocet and Oxycontin that Dr. Matalon had been prescribing since October of 2014.
- 50. Defendant, Linden Care, knowingly and/or recklessly disregarded the terms and conditions of the TIRF-REMS program and filled the prescription for and dispensed the 600 mcg of Subsys and had it shipped in a large carton via Federal Express to Sarah's doorstep
- Dr. Matalon continued the prescriptions of Subsys for Sarah, in addition to the other narcotics, every month thereafter and Linden Care on a monthly basis would accept the Subsys scripts via facsimile and then ship the Subsys via Federal Express to Sarah's doorstep.
- 52. On October 28, 2015, Sarah was admitted to Virtua Hospital in Voorhees, New Jersey suffering from hyper-sedation with hypoxia secondary to narcotics and sedatives. She was immediately taken off Subsys. Sarah was discharged on October 30, 2015 with instructions to discontinue all use of Subsys and to wean off Oxycontin on an outpatient basis. These medical records were immediately provided to Dr. Matalon by the attending physician at Virtua.
- 53. Despite being notified directly by the physicians at Virtua Hospital as to the adverse health effects Sarah was experiencing from Subsys and other drugs she was prescribing, Dr. Matalon ignored this crucial information and just continued to prescribe Subsys, Percocet, Oxycontin and Alprazolam to Sarah over the ensuing five (5) months with the last set of prescriptions written by Dr. Matalon being March 17, 2016.
- 54. On March 25, 2016, Sarah Fuller died due to an adverse reaction to prescription medications,

namely fentanyl (Subsys) and alprazolam, which were prescribed by Dr. Matalon and filled and dispenses by Linden Care.

## FIRST COUNT Negligence-Wrongful Death

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Defendants, Vivienne Matalon, M.D. and TLC Healthcare 2, LLC

- 55. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 56. Defendant, Dr. Matalon, acting as the principal for TLC Healthcare, held herself out to the public and Sarah Fuller and her family as a physician who possessed the skill, knowledge and competency in providing proper and safe medical care and whom would do no harm to her patients, including Sarah Fuller.
- 57. As a result of the reckless, wanton, careless and negligent actions of Dr. Matalon, Sarah Fuller became addicted to/dependent upon the Subsys, Alprazolam, and other dangerous Schedule II narcotics that were repeatedly being prescribed without medical justification and ultimately died do to an adverse reaction to fentanyl (Subsys) and alprazolam.
- 58. At all times relevant hereto Dr. Matalon was subject to various New Jersey Regulations that set forth minimal standards that health care providers must follow when prescribing patients Schedule II narcotics and other controlled substances.
- 59. Dr. Matalon repeatedly disregarded and violated said regulations, including but not limited to, N.J.A.C. 13:35-7.1A & N.J.A.C. 13:35.7.6, by failing to conduct appropriate and timely examinations, failing to develop an appropriate treatment plan, failing to order appropriate testing and by failing to make appropriate specialist referrals.
- Or. Matalon not only violated the applicable New Jersey Regulations, she also violated the acceptable and appropriate standard of care that she owed to Sarah Fuller and she recklessly violated the TIRF-REMS access program by prescribing Subsys to Sarah whom she knew did not have cancer and breakthrough pain that emanated from cancer.

- 61. At the time of Decedent, Sarah A. Fuller's death, she was survived by her parents, Deborah Fuller and David Fuller and her sister, Barbara Fuller.
- 62. At the time of Decedent, Sarah A. Fuller's death and by reason of that wrongful death, Plaintiffs and all surviving family members and beneficiaries have suffered pecuniary losses and losses of household services and all are pursuing this applicable cause of action under and by virtue of the New Jersey Wrongful Death Statute known and designated as N.J.S.A. 2A:31-1 through 6.
- 63. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of Defendants and consisted of, but is not limited to, the following:
  - (a) failure to provide necessary medical information to Sarah Fuller regarding schedule II narcotic drug side effects, including the extreme danger of addiction;
  - (b) prescribing dangerous, addictive and deadly combinations of Schedule II narcotics when Dr. Matalon knew that Sarah had once had a history of addiction;
  - (c) failure to communicate in a timely and proper manner regarding Ms. Fuller's condition with the patient and to provide safe methods of treatment and the development of a reasonable and safe treatment plan;
  - (d) failure to properly diagnose and monitor Ms. Fuller's medical condition and use of Oxycodone, Oxycontin, Percocet and Alprazolam.
  - (e) failure to order appropriate blood work and diagnostic tests for Ms. Fuller;
  - (f) failure to take a proper history on Ms. Fuller and obtain necessary medical records before prescribing narcotics;
  - (g) failure to formulate an accurate, independent diagnosis of any health condition of Ms. Fuller that warranted the extreme and dangerous prescribing

- of narcotic medications;
- (h) failure to make proper medical decisions regarding the treatment of Ms.Fuller that would not subject her to severe risk of harm;
- (i) by prescribing/dispensing unreasonable/dangerous amounts of narcotic medications and allowing representatives of the drug manufacturer to meet with and take part in the treatment of the patient.
- (j) failing to take into account prior medical conditions or risk factors before prescribing narcotic medications;
- (k) prescribing and dispensing extreme amounts of narcotic medication that would clearly cause addiction and serious side effects; and, allowing sales representatives of the drug manufacturer to influence the care and treatment of the patient,
- (1) failing to development alternative treatment regimens to reduce the usage of narcotic medication;
- (m) failing to obtain and review prior and concurrent physician records for decedent to gain any understanding of their opinions and recommended treatments;
- (n) failing to keep adequate records that should have included completing a thorough history and physical and documenting progress with treatment or lack thereof,
- (o) failing to develop a safe and effective treatment plan;
- failing to refer Ms. Fuller to appropriate specialists when any treatment she
   was providing was not effective;
- (q) failing to perform required and necessary physical examinations throughout the course of Ms. Fuller's extended period of receiving prescriptions for narcotic medication;

- (r) failing to conform to the applicable regulations that set forth minimum standards and protocols to ensure safe prescribing of narcotic medication;
- (s) practicing a medical specialty in which Defendants were not trained and were not qualified.
- (t) by continually prescribing dangerous and escalating amounts of narcotic medication without any medical justification or explanation when it was known or it should have known that serious adverse health effects were occurring;
- (u) permitting a sales representative from Insys to met with Sarah Fuller during the doctor/patient relationship in the office and allowing the sales representative to provide false and inaccurate information about the true indication for Subsys along with false and misleading information about the true risks of Subsys
- (v) failing to wean Ms. Fuller from dangerous and deadly narcotic medications when they knew or should have known of the severe risk of harm that would result;
- (w) by prescribing multiple, powerful and dangerous respiratory suppressant drugs at the same time when Defendants knew or should have known of the severe risk of harm of said drugs shutting down the respiratory system:
- immediate release spray fentanyl that was only indicated and approved for cancer patients experiencing breakthrough pain from their malignant cancer; knowing that Ms. Fuller did not have cancer, knowing the use of said drug was contraindicated, contrary to FDA requirements and posed an unreasonable risk of harm to Ms. Fuller;
- (y) negligence/recklessness/wantonness as a matter of law.

On behalf of the wrongful death beneficiaries, the Administrators, Deborah Fuller and David Fuller, claims damages for the full damages allowed under the Wrongful Death Statute and all decisional law interpreting said statute.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendants, Vivienne Matalon, M.D. and TLC Healthcare 2, LLC, individually, jointly severally and/or in the alternative, under the Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

## SECOND COUNT Negligence-Survival Action

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Defendants, Vivienne Matalon, M.D. and TLC Healthcare 2, LLC

- Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- Defendant, Dr. Matalon, acting as the principal for TLC Healthcare, held herself out to the public and Decedent as a physician who possessed the skill, knowledge and competency in providing proper and safe medical care and whom would do no harm to her patients, including Sarah Fuller.
- As a result of the reckless, wanton, careless and negligent actions of Dr. Matalon, Sarah Fuller became addicted to/dependent upon the Subsys, Alprazolam, and other dangerous Schedule II narcotics that were repeatedly being prescribed without medical justification and ultimately died do to an adverse reaction to fentanyl (Subsys) and alprazolam.
- 68. At all times relevant hereto Dr. Matalon was subject to various New Jersey Regulations that set forth minimal standards that health care providers must follow when prescribing patients Schedule II narcotics and other controlled substances.
- 69. Dr. Matalon repeatedly disregarded and violated said regulations, including but not limited

- to, N.J.A.C. 13:35-7.1A & N.J.A.C. 13:35.7.6, by failing to conduct appropriate and timely examinations, failing to develop an appropriate treatment plan, failing to order appropriate testing and by failing to make appropriate specialist referrals.
- 70. Dr. Matalon not only violated the applicable New Jersey Regulations, she also violated the acceptable and appropriate standard of care that she owed to Sarah Fuller and she recklessly violated the TIRF-REMS access program by prescribing Subsys to Sarah whom she knew did not have cancer and breakthrough pain that emanated from cancer.
- 71. At the time of Decedent, Sarah A. Fuller's death, she was survived by her parents, Deborah Fuller and David Fuller and her sister, Barbara Fuller.
- 72. At the time of Decedent, Sarah A. Fuller's death and by reason of that wrongful death, Plaintiffs and all surviving family members and beneficiaries have suffered pecuniary losses and losses of household services and all are pursuing this applicable cause of action under and by virtue of the New Jersey Wrongful Death Statute known and designated as N.J.S.A. 2A:31-1 through 6.
- 73. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of Defendants and consisted of, but is not limited to, the following:
  - (a) failure to provide necessary medical information to Sarah Fuller regarding schedule II narcotic drug side effects, including the extreme danger of addiction;
  - (b) prescribing dangerous, addictive and deadly combinations of Schedule II narcotics when Dr. Matalon knew that Sarah had once had a history of addiction;
  - (c) failure to communicate in a timely and proper manner regarding Ms. Fuller's condition with the patient and to provide safe methods of treatment and the development of a reasonable and safe treatment plan;

- (d) failure to properly diagnose and monitor Ms. Fuller's medical condition and use of Oxycodone, Oxycontin, Percocet and Alprazolam.
- (e) failure to order appropriate blood work and diagnostic tests for Ms. Fuller;
- (f) failure to take a proper history on Ms. Fuller and obtain necessary medical records before prescribing narcotics;
- (g) failure to formulate an accurate, independent diagnosis of any health condition of Ms. Fuller that warranted the extreme and dangerous prescribing of narcotic medications;
- (h) failure to make proper medical decisions regarding the treatment of Ms.Fuller that would not subject her to severe risk of harm;
- (i) by prescribing/dispensing unreasonable/dangerous amounts of narcotic medications and allowing representatives of the drug manufacturer to meet with and take part in the treatment of the patient.
- (j) failing to take into account prior medical conditions or risk factors before prescribing narcotic medications;
- (k) prescribing and dispensing extreme amounts of narcotic medication that would clearly cause addiction and serious side effects; and, allowing sales representatives of the drug manufacturer to influence the care and treatment of the patient,
- (l) failing to development alternative treatment regimens to reduce the usage of narcotic medication;
- (m) failing to obtain and review prior and concurrent physician records for decedent to gain any understanding of their opinions and recommended treatments;
- (n) failing to keep adequate records that should have included completing a thorough history and physical and documenting progress with treatment or

lack thereof,

- (o) failing to develop a safe and effective treatment plan;
- (p) failing to refer Ms. Fuller to appropriate specialists when any treatment she was providing was not effective;
- (q) failing to perform required and necessary physical examinations throughout the course of Ms. Fuller's extended period of receiving prescriptions for narcotic medication;
- (r) failing to conform to the applicable regulations that set forth minimum standards and protocols to ensure safe prescribing of narcotic medication;
- (s) practicing a medical specialty in which Defendants were not trained and were not qualified.
- (t) by continually prescribing dangerous and escalating amounts of narcotic medication without any medical justification or explanation when it was known or it should have know that serious adverse health effects were occurring;
- (u) permitting a sales representative from Insys to met with Sarah Fuller during the doctor/patient relationship in the office and allowing the sales representative to provide false and inaccurate information about the true indication for Subsys along with false and misleading information about the true risks of Subsys
- (v) failing to wean Ms. Fuller from dangerous and deadly narcotic medications when they knew or should have known of the severe risk of harm that would result;
- (w) by prescribing multiple, powerful and dangerous respiratory suppressant drugs at the same time when Defendants knew or should have known of the severe risk of harm of said drugs shutting down the respiratory system:

- immediate release spray fentanyl that was only indicated and approved for cancer patients experiencing breakthrough pain from their malignant cancer; knowing that Ms. Fuller did not have cancer, knowing the use of said drug was contraindicated, contrary to FDA requirements and posed an unreasonable risk of harm to Ms. Fuller;
- (y) negligence/recklessness/wantonness as a matter of law.
- 74. On behalf of the wrongful death beneficiaries, the Administrators, Deborah Fuller and David Fuller, claims damages for the full damages allowed under the Wrongful Death Statute and all decisional law interpreting said statute.
- 75. On behalf of the beneficiaries of decedent, Deborah Fuller and David Fuller as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah A. Fuller and David Fuller, individually, claim damages for the full damages allowed under the Survival Act and all decisional law interpreting said statute for the pain, suffering, and inconvenience endured by decedent prior to death, including, but not limited to, physical pain and suffering, mental pain and suffering and the fright and mental suffering attributed to the peril leading to decedent's death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendants, Vivienne Matalon, M.D. and TLC Healthcare 2, LLC, individually, jointly severally and/or in the alternative, under the Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

## THIRD COUNT

## Negligence-Wrongful Death

Plaintiffs, Deborah Fuller and David Fuller, as Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v.

Defendant Insys Therapeutics, Inc.

- 76. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 77. At the time of Decedent, Sarah A. Fuller's death, she left surviving her mother and father, Deborah Fuller and David Fuller, and her sister, Barbara Fuller.
- 78. At the time of decedent, Sarah A. Fuller's death and by reason of that wrongful death, Plaintiffs and all surviving family members and beneficiaries have suffered pecuniary losses and loss of household services and all are pursuing this applicable cause of action under and by virtue of the New Jersey Wrongful Death Statute known and designated as N.J.S.A. 2A:31-1through 6.
- 79. The actions of the Defendant, Insys, as aforesaid constitute fraud, deception, misrepresentation, wantonness, negligence and gross negligence that endangered the life, safety, health and welfare of the general public and Sarah A. Fuller.
- 80. The grievous injuries, pain, suffering and ultimate death of Sarah A. Fuller, were caused solely and exclusively by the negligence and other wrongful conduct of Defendant, jointly, severally and/or individually, and/or by their agents, servants, and employees.
- 81. The liability of the Defendant is predicated upon individual acts and/or on principles of respondent superior and the Defendant is liable individually, jointly, severally and/or in the alternative.
- 82. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of Defendant and consisted of, but is not limited to, the following:
  - (a) failure to provide accurate and necessary medical information to Sarah Fuller regarding drug side effects, including the extreme danger of addiction and

death;

- (b) failure to provide accurate and necessary medical information to health care providers and others to lure patients into ingesting Subsys;
- (c) Marketing and selling Subsys, a powerful, highly addictive, highly dangerous and lethal drug to Sarah Fuller and the public, for off label use when it knew Ms. Fuller did not have any condition for which Subsys was ever intended to be used;
- (d) engaging in unlawful, deceptive, fraudulent and reckless marketing of Subsys to Sarah Fuller knowing that her use of the product was inappropriate, highly dangerous, contraindicated and forbidden by the FDA;
- (e) marketing Subsys by targeting medical providers/prescribers knowing said medical providers treated few, if any, cancer patients and specifically marketing the product for conditions other than "breakthrough cancer pain", in an effort to increase sales;
- (f) using false and deceptive marketing in an effort to affirmatively mislead the medical community, the public, health plans, as well as the Decedent, in order to increase sales;
- (g) pre-populating TIRF-REMS documents and other Insys created forms in order to mislead physicians into prescribing Subsys for unapproved indications and then obtaining payment for the off-label prescriptions;
- (h) marketing, promoting and encouraging the use Subsys to Decedent knowing she did not suffer from breakthrough cancer pain and without regard to the extreme risk to decedent's health and well being it posed;
- (i) intentionally ignoring the FDA requirement mandating the lowest possible dose for Subsys, instead promoting and encouraging a much higher and much more dangerous "effective dose" solely to maximize profits and

commissions.

- (j) mandating and encouraging its salespersons to interfere with the doctor/patient relationship and personally meet with patients, including Sarah Fuller, and making material misrepresentations in regard to the sole indication for Subsys and the true risks associated with the drug;
- (k) paying kickbacks and other financial incentives to physicians in its speakers program in order to have those paid speakers promote its false and misleading information about the proper indications for Subsys and its true risks in order to persuade the medical community to prescribe Subsys;
- (l) fraudulently providing assistance to patients, physicians and pharmacies in obtaining preauthorization and approval from Medicare and insurance companies for payment of Subsys for the treatment of off label conditions for which it is neither indicated nor safe..
- (m) failing to warn Ms. Fuller of the true risks of Subsys and that it was never proven safe for non-cancer related pain;
- (n) negligence/recklessness/wantonness as a matter of law.
- 83. On behalf of the beneficiaries of decedent, Deborah Fuller and David Fuller, as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, claim damages for the full damages allowed under the Wrongful Death Act and all decisional law interpreting said statute for the pain, suffering, and inconvenience endured by decedent prior to death, including, but not limited to, physical pain and suffering, mental pain and suffering and the fright and mental suffering attributed to the peril leading to decedent's death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendant, Insys Therapeutics, Inc., under the

Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

## FOURTH COUNT Negligence-Survival Action

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, and Deborah Fuller and David Fuller, individually, Defendant Insys Therapeutics, Inc.

- 84. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 85. At the time of Decedent, Sarah A. Fuller's death, she left surviving her mother and father,
  Deborah Fuller and David Fuller, and her sister, Barbara Fuller.
- 86. At the time of decedent, Sarah A. Fuller's death and by reason of that wrongful death, Plaintiffs and all surviving family members and beneficiaries have suffered pecuniary losses and loss of household services and all are pursuing this applicable cause of action under and by virtue of the New Jersey Wrongful Death Statute known and designated as N.J.S.A. 2A:31-1through 6.
- 87. The actions of the Defendant, Insys, as aforesaid constitute fraud, deception, misrepresentation, wantonness, negligence and gross negligence that endangered the life, safety, health and welfare of the general public and Sarah A. Fuller.
- 88. The grievous injuries, pain, suffering and ultimate death of Sarah A. Fuller, were caused solely and exclusively by the negligence and other wrongful conduct of Defendant, jointly, severally and/or individually, and/or by their agents, servants, and employees.
- 89. The liability of the Defendant is predicated upon individual acts and/or on principles of respondent superior and the Defendant is liable individually, jointly, severally and/or in the alternative.
- 90. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of Defendant and consisted of, but is not limited to, the following:

- failure to provide accurate and necessary medical information to Sarah Fuller regarding drug side effects, including the extreme danger of addiction and death;
- (b) failure to provide accurate and necessary medical information to health care providers and others to lure patients into ingesting Subsys;
- (c) marketing and selling Subsys, a powerful, highly addictive, highly dangerous and lethal drug to Sarah Fuller for off label use when it knew Ms. Fuller did not have any condition for which Subsys was ever intended to be used;
- (d) engaging in unlawful, deceptive, fraudulent and reckless marketing of Subsys to Sarah Fuller and the public knowing that her use of the product was inappropriate, highly dangerous, contraindicated and forbidden by the FDA;
- (e) Marketing Subsys by targeting medical providers/prescribers knowing said medical providers treated few, if any, cancer patients and specifically marketing the product for conditions other than "breakthrough cancer pain", in an effort to increase sales;
- (f) using false and deceptive marketing in an effort to affirmatively mislead the medical community, the public, health plans, as well as the Decedent, in order to increase sales;
- (g) pre-populating TIRF-REMS documents and other Insys created forms in order to mislead physicians into prescribing Subsys for unapproved indications and then obtaining payment for the off-label prescriptions;
- (h) marketing, promoting and encouraging the use Subsys to Decedent knowing she did not suffer from breakthrough cancer pain and without regard to the extreme risk to decedent's health and well being it posed;
- (i) intentionally ignoring the FDA requirement mandating the lowest possible dose for Subsys, instead promoting and encouraging a much higher and much

- more dangerous "effective dose" solely to maximize profits and commissions.
- (j) mandating and encouraging its salespersons to interfere with the doctor/patient relationship and personally meet with patients, including Sarah Fuller, and making material misrepresentations in regard to the sole indication for Subsys and the true risks associated with the drug;
- (k) paying kickbacks and other financial incentives to physicians in its speakers program in order to have those paid speakers promote its false and misleading information about the proper indications for Subsys and its true risks in order to persuade the medical community to prescribe Subsys;
- (l) fraudulently providing assistance to patients, physicians and pharmacies in obtaining preauthorization and approval from Medicare and insurance companies for payment of Subsys for the treatment of off label conditions for which it is neither indicated nor safe..
- (m) failing to warn Ms. Fuller of the true risks of Subsys and that it was never proven safe for non-cancer related pain;
- (n) negligence/recklessness/wantonness as a matter of law.
- 91. On behalf of the beneficiaries of decedent, Deborah Fuller and David Fuller, as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, claim damages for the full damages allowed under the Wrongful Death Act and all decisional law interpreting said statute for the pain, suffering, and inconvenience endured by decedent prior to death, including, but not limited to, physical pain and suffering, mental pain and suffering and the fright and mental suffering attributed to the peril leading to decedent's death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller,

individually, demand damages and judgment against Defendant, Insys Therapeutics, Inc., exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

# FIFTH COUNT Negligence-Wrongful Death Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Defendant, Linden Care, LLC

- 92. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 93. At the time of Decedent, Sarah A. Fuller's death, she left surviving her mother and father,
  Deborah Fuller and David Fuller, and her sister, Barbara Fuller.
- 94. At the time of decedent, Sarah A. Fuller's death and by reason of that wrongful death, Plaintiffs and all surviving family members and beneficiaries have suffered pecuniary losses and loss of household services and all are pursuing this applicable cause of action under and by virtue of the New Jersey Wrongful Death Statute known and designated as N.J.S.A. 2A:31-1through 6.
- 95. The actions of the Defendant, Linden Care, as aforesaid constitute fraud, deception, misrepresentation, wantonness, negligence and gross negligence that endangered the life, safety, health and welfare of the general public and Sarah A. Fuller.
- 96. The grievous injuries, pain, suffering and ultimate death of Sarah A. Fuller, were caused solely and exclusively by the negligence and other wrongful conduct of Defendant, jointly, severally and/or individually, and/or by their agents, servants, and employees.
- 97. The liability of the Defendant is predicated upon individual acts and/or on principles of respondent superior and the Defendant is liable individually, jointly, severally and/or in the alternative.
- 98. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of

Defendant and consisted of, but is not limited to, the following:

- (a) manipulation and subversion of the TIRF-REMS access program by falsely certifying that it knew Subsys was only indicated for breakthrough pain as a result of malignant cancer and that was the only medical condition for which it would dispense Subsys knowingly causing a serious risk or harm and death;
- (b) assisting Insys with its scheme of marketing, promoting and encouraging the medical community to prescribe Subsys for unapproved indications by ensuring Insys that it would fill and dispense and ultimately did fill and dispense hundreds of thousand of off-label prescriptions for Subsys throughout the country, including those for Sarah Fuller;
- (c) violating New Jersey regulations regarding the dispensing of a schedule II narcotic by accepting prescriptions for Subsys via facsimile and dispensing upon the receipt of that faxed prescription;
- (d) violating FDA prescribing/describing requirements for Subsys as well as the TIRF-REMS access program by filling an dispensing an initial prescription of Subsys at 200 mcg for Sarah Fuller;
- (e) violating FDA prescribing/describing requirements for Subsys as well as the TIRF-REMS access program by filling an dispensing the second prescription of Subsys for Sarah Fuller for 600 mcg, triple the initial prescription that it dispenses less than one month earlier;
- (f) directly knowing or should have known that it was regularly filling and dispensing prescriptions for Subsys for unapproved indications, including Sarah Fuller which it knew caused a serious risk of harm and death;
- (g) knowing that the amount of Subsys that it was dispensing throughout the country from 2012-2016 increased drastically and that the increase was due to prescriptions being written off-label for non-cancer related pain, including

those for Sarah Fuller;

- (h) failing to train, oversee and manage its employees for the proper, safe and lawful dispensing of Subsys for its patients throughout the country, including Sarah Fuller.
- (i) negligence/recklessness/wantonness as a matter of law.
- 99. On behalf of the beneficiaries of decedent, Deborah Fuller and David Fuller, as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, claim damages for the full damages allowed under the Wrongful Death Act and all decisional law interpreting said statute for the pain, suffering, and inconvenience endured by decedent prior to death, including, but not limited to, physical pain and suffering, mental pain and suffering and the fright and mental suffering attributed to the peril leading to decedent's death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendant, Linden Care, LLC under the Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

### SIXTH COUNT Negligence-Survival Action

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Defendants, Linden Care, LLC

- 100. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 101. Plaintiffs, Deborah Fuller and David Fuller, as Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually bring this Survival Action on behalf of the Estate of Sarah A. Fuller, deceased under and by virtue of N.J.S.A. 2A:31-4.

- 102. As a result of the acts and omissions of Defendants, the negligence, recklessness and wantonness of Defendants, Plaintiff's decedent was caused significant pain and suffering and anguish for a lengthy period before her death resulting in the entitlement to damages by said beneficiaries under the Survival Act.
- 103. The injuries/death sustained by decedent, as aforesaid, were directly and proximately caused by the negligent, careless, wanton, willful and reckless conduct of Defendant and consisted of, but is not limited to, the following:
  - (a) manipulation and subversion of the TIRF-REMS access program by falsely certifying that it knew Subsys was only indicated for breakthrough pain as a result of malignant cancer and that was the only medical condition for which it would dispense Subsys;
  - (b) assisting Insys with its scheme of marketing, promoting and encouraging the medical community to prescribe Subsys for unapproved indications by ensuring Insys that it would fill and dispense and ultimately did fill and dispense hundreds of thousand of off-label prescriptions for Subsys throughout the country, including those for Sarah Fuller knowing causing a serious risk or harm and death;
  - (c) violating New Jersey regulations regarding the dispensing of a schedule II narcotic by accepting prescriptions for Subsys via facsimile and dispensing upon the receipt of that faxed prescription;
  - (d) violating FDA prescribing/describing requirements for Subsys as well as the TIRF-REMS access program by filling an dispensing an initial prescription of Subsys at 200 mcg for Sarah Fuller;
  - (e) violating FDA prescribing/describing requirements for Subsys as well as the TIRF-REMS access program by filling an dispensing the second prescription of Subsys for Sarah Fuller for 600 mcg, triple the initial prescription that it

- dispenses less than one month earlier;
- (f) directly knowing or should have known that it was regularly filling and dispensing prescriptions for Subsys for unapproved indications, including Sarah Fuller which subject her to serious risk of harm and death;
- (g) knowing that the amount of Subsys that it was dispensing throughout the country from 2012-2016 increased drastically and that the increase was due to prescriptions being written off-label for non-cancer related pain, including those for Sarah Fuller;
- (h) failing to train, oversee and manage its employees for the proper, safe and lawful dispensing of Subsys for its patients throughout the country, including Sarah Fuller.
- (i) negligence/recklessness/wantonness as a matter of law.
- 104. On behalf of the beneficiaries of decedent, Deborah Fuller and David Fuller as the Administrators Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah A. Fuller and David Fuller, individually, claim damages for the full damages allowed under the Survival Act and all decisional law interpreting said statute for the pain, suffering, and inconvenience endured by decedent prior to death, including, but not limited to, physical pain and suffering, mental pain and suffering and the fright and mental suffering attributed to the peril leading to decedent's death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendant, Linden Care, LLC, under the Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

#### <u>SEVENTH COUNT</u> COMMON LAW FRAUD

## Deborah Fuller and David Fuller, as Administrators of the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller individually v. Insys Therapeutics, Inc. and Linden Care, LLC

- 105. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein.
- 106. The Defendants Insys and Linden Care, independently and collectively, falsely and fraudulently represented to the public and specifically to Sarah Fuller and her family that the drug, Subsys, was indicated and found to be safe and effective for the treatment of non-cancer pain when they knew it was only approved by the FDA for the very limited purpose of treating patients with breakthrough cancer pain. The Defendants colluded to in having Subsys prescribed and dispensed regularly and systematically throughout the country for people that did not have cancer and for which Subsys was extremely deadly and dangerous, including Sarah Fuller.
- 107. The representations made by Defendants were, in fact, false and when the Defendants made their representations they knew they were false and they willfully, wantonly, and recklessly disregarded the extreme danger of causing serious illness, addiction and death to non-cancer patients who used Subsys. Moreover, these false representations were carried out through Defendants' manipulation, subversion and violation of the TIRF-REMS access program.
- 108. The false representations made by Defendants were carried out with the intent to defraud and deceive the Plaintiffs, the decedent, and the public for the sole purpose of increasing prescriptions, sales and consumption of Subsys to increase Defendant's profits, all of which evidenced a callous, willful, reckless and depraved indifference to the health, safety and welfare of the decedent, Sarah A. Fuller and the public.
- 109. At the time the misrepresentations were made the by Defendants, the Plaintiffs herein and the decedent, Sarah A. Fuller, were unaware of the falsity of those representations and reasonably relied upon the false representations of defendants.
- 110. In reliance upon the Defendant's false representations the decedent, Sarah A. Fuller, was

- induced into using Subsys for the treatment of a condition for which it was not approved and clearly was not safe, believing it to be safe, appropriate and effective.
- 111. Had the Decedent, Sarah A. Fuller, known the true facts that Subsys was only approved for treatment of patients with breakthrough cancer pain and that Subsys was never tested, proven to be effective, safe nor approved by the FDA for her condition, she would never have used the drug.
- 112. The Defendants' wrongful conduct constitutes fraud, deceit and was committed and perpetrated willfully, wantonly, and purposely upon Decedent, Sarah A. Fuller.
- 113. As a direct result of Defendants fraudulent conduct, Decedent, Sarah A. Fuller, was caused grievous sickness, suffering, addiction and untimely death.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand punitive damages and judgment against Defendants, Insys Therapeutics, Inc and Linden Care LLC, individually, jointly severally and/or in the alternative exclusive of prejudgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

#### EIGHTH COUNT NEGLIGENT MISREPRESENTATION

<u>Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Insys Therapeutics, Inc. and Linden Care, LLC</u>

- 114. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
- 115. The Defendants herein had a duty to accurately and truthfully represent to the public and the Decedent herein that Subsys was only approved to be safe and effective for the treatment of patients with cancer pain from malignancies and that it was not approved by the FDA as safe and effective for the treatment of non-cancer pain and it would not be marketed and dispensed otherwise.

- 116. The Defendants, through the TIRF-REMS access program and certifications, agreed and certified that Subsys would only be prescribed and dispensed solely for patients suffering breakthrough pain due to malignant cancer; yet the Defendants manipulated and violated said provisions and requirements.
- 117. The representations made by the Defendants through their multiple unlawful and fraudulent acts were, in fact, false. Decedent, Sarah Fuller, reasonably relied upon Defendants' negligent misrepresentations which led her to unknowingly consuming Subsys for which it was not indicated for her and instead posed extreme risk or harm and death.
- 118. The Defendants failed to exercise reasonable and ordinary care in making their representations to the public and the Decedent concerning Subsys while they were marketing, promoting, selling and distributing, and dispensing Subsys to the public and the Decedent and the Defendants' intent and purpose was for the medical community to prescribe Subsys and consumers to ingest Subsys for medical conditions that were unapproved and for which the drug was unsafe and ineffective all for their financial benefit..
- 119. As a foreseeable, direct and proximate result of the negligent misrepresentations of the Defendants to the medical community, the general public, and the Decedent, the Decedent relied upon said misrepresentations and believed it was to take Subsys for her non-cancer pain.
- 120. The grievous suffering, injuries and death of Sarah A. Fuller were proximately caused by and/or contributed to by the negligence, fraud, wantonness, recklessness and intentional wrongful behavior of the defendants, their agents, servants and/or employees, and were due in no manner whatsoever to any act or failure to act on the part of Sarah A. Fuller.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages, compensatory and punitive damages, and judgment against Defendants, Insys Therapeutics, Inc and Linden Care Comprehensive Pharmaceutical Services, Inc.,

individually, jointly severally and/or in the alternative, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

## **NINTH COUNT**

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Defendants John Doe 1-10 (fictitious) and ABC Corporation 1-10 (fictitious)

- 121. Plaintiffs incorporate the previous paragraphs in this count as fully set forth herein at length and are asserting all causes of action that were previously stated against all of the specifically named Defendant under each and every count.
- 122. Defendant John Doe 1-10 (fictitious) are the fictitious names of physicians, doctors or other health care providers, duly licensed to practice in the state of New Jersey, who, at all times relevant hereto, were engaged in the practice of their profession and provided medical services to Sarah A. Fuller for profit including but not limited to issuing prescriptions for narcotics and other dangerous drugs.
- 123. Defendant, ABC Corporation 1-10 (fictitious), is a New Jersey corporate/business entity, professional association, partnership and/or medical practice that at all times relevant hereto was providing health care services and/or pharmaceutical services for profit in the State of New Jersey. ABC Corporation 1-10 provided health care services to further it's business interests.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendants, John Doe 1-10 (fictitious) and ABC Corporation 1-10 (fictitious) individually, jointly severally and/or in the alternative, under the Wrongful Death Act, exclusive of pre-judgment interest, post-judgment interest, costs, counsel fees and all other damages allowable by law.

# <u>TENTH COUNT</u> PUNITIVE DAMAGES

Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually v. Vivienne Matalon, M.D., TLC Healthcare 2, LLC, Insys Therapeutics, Inc. and Linden Care, LLC, Inc., John Doe # 1-10 (fictitious) and ABC Corporation #1-10 (fictitious)

- 124. Plaintiffs incorporate the previous paragraphs at length in this count as though fully set forth herein at length.
- 125. Defendants knew or should have known that their actions with the marketing, prescribing and dispensing of Subsys posed a significant risk of serious health problems and/or death and their actions, individually and collectively were wanton and reckless and in wilful disregard to the rights and safety of Decedent, Sarah A. Fuller.
- 126. As a result of the reckless and wanton acts and omissions of Defendants, individually and collectively, Decedent, Sarah Fuller, was caused significant pain and suffering and anguish for a lengthy period of time which then ultimately led to her death.
- 127. The injuries/death sustained by Decedent, Sarah Fuller, as aforesaid, were directly and proximately caused by the wanton, wilful and reckless conduct of Defendants as fully set forth in detail throughout Plaintiff's Complaint.

WHEREFORE, Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, individually, demand damages and judgment against Defendants, Vivienne Matalon, M.D., TLC Healthcare, Insys Therapeutics, Inc, Linden Care, LLC., John Doe M.D., 1-10, (fictitious) ABC Medical Group 1-10, (fictitious) ABC Corporation 1-10, (fictitious), for punitive damages, together with interest, attorney's fees and costs of suit as well as any other damages the court deems just and are allowable by law.

# **DESIGNATION OF TRIAL COUNSEL**

Pursuant to the provision of R.4:25-4, notice is given that RICHARD J. HOLLAWELL, ESQUIRE and MARK C. DEWLAND are hereby designated as trial counsel.

# **DEMAND FOR JURY**

PLEASE TAKE NOTICE that the Plaintiffs hereby demands a jury trial as to all of the within issues.

## DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

Pursuant to R. 4:10-2(b), demand is hereby made that you disclose to the undersigned whether there are any insurance agreements or policies under which any person or entity carrying on an insurance business may be liable to satisfy part or all of a judgment which may be entered in this action or to indemnify or reimburse for payments made to satisfy the judgment.

If so, provide to the undersigned a copy of each policy or agreement, or in the alternative state, under oath or certification; (a) policy number; (b) name and address of insurer; ©) inception and expiration dates; (d) names and addresses of all persons/entities covered; (e) personal injury limits; (f) property damage limits; (g) medical payment limits.

# **DEMAND FOR DISCOVERY**

Pursuant to R..4:17-1(b), demand is hereby made for each Defendant to provide answers to Form C and Form C(3) Interrogatories of Appendix II of the New Jersey Court Rules.

#### NOTICE OF NO OTHER ACTION

Pursuant to Rule 4:5-1 the Plaintiffs' attorney hereby certifies to the best of his knowledge that there is an Order to Show Cause seeking, inter alia, presuit discovery in this matter pending in Camden County Superior Court, Docket No: L-870-17, that will be rendered moot by the filing of this action.

DATED: 3/23/17

DATED: 3/23/2017

Richard J. Hollawell richard j. hollawell, esquire

MARK C. DEWLAND. ESQUIRE

Attorneys for Plaintiffs, Deborah Fuller and David Fuller, as Administrator Ad Prosequendum for the Estate of Sarah A. Fuller, deceased, and Deborah Fuller and David Fuller, Individually

Docket No.: 2016-1491

# State of New Jersey Camden County Surrogate's Court

In the matter of the Estate Sarah A Fuller, Deceased LETTERS ADMINISTRATION
AD PROSEQUENDUM

I, Michelle A. Gentek-Mayer, Surrogate of Camden County and State of New Jersey, do hereby certify that on September 29, 2016, administration ad prosequendum of decedent, who died intestate, late of the County of Camden and State of New Jersey was granted by me to Deborah S Fuller and David C Fuller of said County of Camden who is duly authorized to bring an action, institute a proceeding or make a claim in his name as such administrator ad prosequendum as is the statute such case provided.



WITNESS my hand and seal of office on

September 29, 2016

Surrogate

#### **AFFIDAVIT OF MERIT**

- I, Kevin E. Bell, M.D., being of full age, sound mind and being duly sworn upon his oath, according to law, hereby deposes and says:
- 1. I am a medical doctor specializing in Internal Medicine and licensed to practice medicine in the State of New Jersey. The opinions which I am rendering in this Affidavit of Merit relate to substantially the same areas of medicine in which I practice.
- 2. I have reviewed the medical records and pharmacy records regarding the treatment rendered to Sarah Ann Fuller by Vivienne I. Matalon, M.D. and other providers at TLC Health Care.
- 3. It is my opinion to a reasonable degree of medical certainty that, more likely than not, Vivienne I. Matalon, M.D. and TLC Health Care failed to use such care as a reasonably prudent and careful health care provider would have used under similar or same circumstances, as she was negligent (she failed to use that level of skill and learning which is ordinarily used under the same or similar circumstances by members of Dr. Vivienne I. Matalon's profession) and was actually reckless in the over-prescribing of narcotic medications without performing thorough physical examinations and without objective evidence to support the prescribing of the narcotic medications and for failing to implement a careful and cognizable treatment plan as required for the ongoing prescribing of Schedule II narcotics.
- 4. It is my opinion to a reasonable degree of medical certainty that Sarah Ann Fuller was caused to be severely ill with addiction to the various narcotics being improperly and clearly overprescribed by Vivienne I. Matalon, M.D. and TLC Health Care. Moreover, it is my opinion that the over-prescribing of narcotics by Vivienne I. Matalon, M.D. and TLC Health Care was a significant factor that led to the ultimate demise of Sarah Ann Fuller.

5. I certify that the above statements made by me are true. I am aware that if any of the above statements made by me are willfully false, I am subject to punishment.

KEVIN E. BELL, M.D.

STATE OF NEW JERSEY, COUNTY OF Somercet SS.:

I CERTIFY that on 28<sup>th</sup>ob Nov, 2016, Kevin EBell MD personally came before me and acknowledged under oath, to my satisfaction, that this person (or if more than one, each person):

- (a) is named in and personally signed this document; and
- (b) signed, sealed and delivered this document as his or her act and deed.

MARIETTA A. DEALAMAN NOTARY PUBLIC OF NEW JERSEY 1.D. # 50003472

ty Commission Expires 9/18/2019



# **CERTIFICATE OF MERIT**

I, Joel Shuster, RPh, PharmD, being of full age, sound mind and being duly sworn upon his oath, according to law, hereby deposes and says:

- 1. I am a Doctor of Pharmacy and was Board Certified in Psychiatric Pharmacy for fourteen years. The opinions which I am rendering in this Affidavit of Merit relate to substantially the same areas of pharmacy in which I am licensed.
- 2. I have reviewed the medical records and pharmacy records regarding the medications prescribed to Sarah Ann Fuller by Vivienne I. Matalon, M.D. which were dispensed by Linden Care Pharmacy, 130 Crossways Park Drive, Suite 101, Woodbury, NY 11797.
- 3. It is my opinion to a reasonable degree of pharmaceutical certainty that pharmacists at Linden Care Pharmacy, 130 Crossways Park Drive, Suite 101, Woodbury, NY were negligent and reckless in their duties as pharmacists while dispensing medications to Sarah Ann Fuller and failed to adhere to the acceptable standards of care for pharmacists as well as applicable New Jersey Regulations that govern the safe dispensing of prescription medication.
- 4. It is my opinion to a reasonable degree of pharmaceutical certainty that Sarah Ann Fuller's death from a drug overdose was a direct result of the over-dispensing of narcotics to Sarah Ann Fuller by pharmacists at Linden Care Pharmacy, 130 Crossways Park Drive, Suite 101, Woodbury, NY. Therefore it is my opinion that the over-dispensing of narcotics by pharmacists at Linden Care Pharmacy, 130 Crossways Park Drive, Suite 101, Woodbury, NY was the cause or a contributing factor to the death of Sarah Ann Fuller.
- 5. That such failure to use reasonable care directly caused or directly contributed to cause damages and ultimately death to Sarah Ann Fuller.

6. I certify that the above statements made by me are true. I am aware that if any of the above statements made by me are willfully false, I am subject to punishment.

JOEL SHUSTER, RPh, PharmD

My Comm. Expires
April 10, 2020
No. FF 980567

OF FLORIDA

STATE OF FLORIDA.
COUNTY OF Palm Beach SS.:

I CERTIFY that on Ottober 26, 2016, Joel Shwitel personally came before me and acknowledged under oath, to my satisfaction, that this person (or if more than one, each person):

(a) is named in and personally signed this document; and

(b) signed, sealed and delivered this document as his or her act and deed.