

JS 44 (Rev. 06/17)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

**I. (a) PLAINTIFFS**

Deborah Fuller and David Fuller, Administrators Ad Prosequendum of the Estate of Sarah A. Fuller, Deceased

(b) County of Residence of First Listed Plaintiff Camden County, N.J.  
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Mark C. Dewland, Esq. 540 N. Route 73, Berlin Township, N.J. 08091  
609-472-1377

**DEFENDANTS**

Insys Therapeutics, Inc., John Kapoor, Michael Babich, Alex Burlakoff & Rochester Drug Cooperative, Inc.

County of Residence of First Listed Defendant Arizona  
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)  
Adam Schwartz, Esq.-Insys; Kurt Mullen Esq.-Kapoor; Israel Dahan Esq.-Babich

**II. BASIS OF JURISDICTION** (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

**III. CITIZENSHIP OF PRINCIPAL PARTIES** (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- |   | PTF                                   | DEF                        |   | PTF                        | DEF                                   |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State                   | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State     | <input type="checkbox"/> 4 | <input type="checkbox"/> 4            |
| Citizen of Another State                | <input type="checkbox"/> 2            | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3            | <input type="checkbox"/> 3 | Foreign Nation  | <input type="checkbox"/> 6 | <input type="checkbox"/> 6            |

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input checked="" type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<b>PRISONER PETITIONS</b> <b>Habeas Corpus:</b> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <b>Other:</b> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**V. ORIGIN** (Place an "X" in One Box Only)

- ☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District (specify) ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 U.S.C. 1441(a) Defendant Removed Original State Court Action

Brief description of cause:

Wrongful Death due to Fraudulent Marketing of Pharmaceuticals

**VII. REQUESTED IN COMPLAINT:**

☐ CHECK IF THIS IS A CLASS ACTION DEMAND \$  
UNDER RULE 23, F.R.Cv.P.

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE Steven C. Mannion MJ

DOCKET NUMBER 2:17-cv-07877

DATE 7/17/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

***IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY***

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

CIVIL ACTION

2:17-cv-07877-ES-SCM

INSYS THERAPEUTICS INC., JOHN KAPOOR,  
MICHAEL BABICH, ALEC BURLAKOFF,  
ROCHESTER DRUG CO-OPERATIVE INC.,  
JOHN DOE #1-10 (fictitious)  
& ABC CORPORATION #1-10 (FICTITIOUS), I/J/S/A

**PLAINTIFFS' SECOND  
AMENDED COMPLAINT**

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 183 Bishop Avenue, West Berlin, New Jersey, 08091, by way of complaint against Defendants states as follows:

**JURISDICTION AND VENUE**

This Court is the proper Court of Jurisdiction. All actions herein occurred in Camden County New Jersey and the United States District Court in Camden New Jersey is the 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.”**

2. Decedent, Sarah A. Fuller, who was Deborah Fuller & David Fuller’s daughter, resided at 47 West Temple Avenue, Stratford, New Jersey.
3. 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. 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. Plaintiffs have resolved their professional liability and other claims set forth against Dr. Matalon individually and as the Administrators Ad Prosequendum for the Estate of Sarah Fuller.
7. 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.
8. Defendant, John Kapoor, (“Kapoor”) is an individual residing in Phoenix Arizona. Kapoor is the founder and is the largest shareholder of the Defendant, Insys. At various times from 2012 through 2017 Kapoor held various management positions in the company, including Executive Chairman of the Board of Directors and Chief Executive Officer (“CEO”). Mr. Kapoor at all relevant times was a majority shareholder of Insys stock who profited handsomely from his and other co-defendants fraud.
9. At all times relevant hereto Kapoor was personally responsible for the development, promotion, distribution and sale of the drug Subsys throughout the United States, including the State of New Jersey. At all times relevant hereto Kapoor was personally responsible for directing the day to day scheme carried out by Insys to profit by using bribes and fraud to cause the illicit distribution of Subsys.
10. Defendant, Michael Babich, (“Babich”) is an individual residing in Scottsdale, Arizona.



At various times relevant hereto Babich was President and CEO of the Defendant, Insys. Babich was personally responsible for the management and direction of the development, promotion, distribution and sale of Subsys throughout the United States, including the State of New Jersey. Mr. Babich at all relevant times was a significant shareholder of Insys stock who profited handsomely from his and other co-defendants fraud.

11. At all times relevant hereto Babich was personally responsible for directing the day to day scheme carried out by Insys to profit by using bribes and fraud to cause the illicit distribution of Subsys.
12. Defendant, Alec Burlakoff, ("Burlakoff") is an individual residing in Charlotte, North Carolina. At various times relevant hereto Burlakoff held several executive management positions at Insys, including Vice President of Sales. Burlakoff was personally responsible for the promotion, distribution and sale of Subsys throughout the United States, including the State of New Jersey. Mr. Burlakoff at all relevant times was a significant shareholder of Insys stock who profited handsomely from his and other co-defendants fraud.
13. At all times relevant hereto Burlakoff was personally responsible for directing the day to day scheme carried out by Insys to profit by using bribes and fraud to cause the illicit distribution of Subsys.
14. On October 24, 2017, a First Superceding Indictment was filed against seven (7) top Insys executives on charges relating to their illegal, nationwide conspiracy of bribing doctors and making fraudulent misrepresentations to insurers and pharmacy benefit managers. The named Defendants include Michael Babich, Alec Burlakoff and John

Kapoor. (See First Superseding Indictment in the case of UNITED STATES OF AMERICA v. MICHAEL L. BABICH, ALEC BURLAKOFF, MICHAEL J. GURRY, RICHARD M. SIMON, SUNRISE LEE, JOSEPH A. ROWAN, JOHN N. KAPOOR, Docket No. 16cr10343ADB attached hereto as Exhibit “B”) and incorporated herein by reference. Plaintiffs hereby incorporate the factual allegations and evidence cited in Exhibit “B” as part of this complaint as though specifically set forth herein. Babich and Burlakoff have subsequently entered guilty pleas to the allegations set forth in Ex. B.

15. On November 15, 2017, the State of New Jersey filed an amended Complaint against Insys and John Kapoor in Middlesex County for violation of The New Jersey False Claims Act, N.J.S.A. 2A: 32C-1. et seq., Consumer Fraud, as well as for other claims. (See Amended Complaint in Christopher S. Porrino, Attorney General of the State of New Jersey, on behalf of the State of New Jersey, v. Insys Therapeutics, Inc. a Delaware corporation, and John N. Kapoor, attached Exhibit “C”) and incorporated herein by reference.
16. 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.
17. 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. Linden Care was an integral part of the fraudulent schemes planned, developed and executed by Insys, Kapoor, Babich and Burlakoff in that it would knowingly dispense Subsys to persons to whom it knew it was not intended or approved, including Sarah Fuller. Linden care has been identified as co-conspirator pharmacy number one (1) in the superseded indictment United States of America v. Michael Babich et al. attached as Exhibit "B." Defendants have resolved their claims against Linden Care.

18. 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.
19. The Defendant, Rochester Drug Co-Operative, Inc., ("RDC") is a regional wholesale drug cooperative headquartered in Rochester, New York who at all times relevant hereto, distributed highly addictive controlled dangerous substances to independently owned pharmacies in several states, including Linden Care.
20. As a distributor of controlled dangerous substances, RDC is required to operate a system to report to the DEA suspicious orders of controlled dangerous substances pursuant to 21 C.F.R. §1301.74(b).
21. Laurence F. Doud III ("Doud") was Chief Executive Officer of RDC from 1991 until

2017. At all times relevant hereto Doud was acting on behalf of, and as the agent, servant and employee of RDC.

22. From May 2012 through November 2016 RDC received and filled over 1.5 million orders for controlled dangerous substances from its pharmacy customers, including Linden Care. During this period of time RDC reported a total of only four suspicious orders to the DEA notwithstanding its legal obligation under the Controlled Substances Act. During this period of time RDC failed to report at least two thousand suspicious orders of controlled substances made by its pharmacy customers, specifically Linden Care. RDC was one of the nation's top dispensers of Subsys and was the exclusive dispenser of Subsys to Linden Care.
23. On April 23, 2019, the case of United States of America v. Rochester Drug Co-Operative, Inc., was filed in the United States District Court for the Southern District of New York seeking injunctive relief and damages for multiple violations of their failure to report the aforementioned suspicious activity. ( See Complaint Docket No. 1:19-cv-03568 attached hereto as Exhibit "D") Paragraph 25 of the government's complaint specifically references RDC's actions in reference to Linden Care. Plaintiffs hereby incorporate the factual allegations and evidence cited in Exhibit "D" as part of this complaint as though specifically set forth herein.
24. At all times relevant hereto, RDC, through their agents, servants and/or employees, including but not limited to Doud, negligently, intentionally and fraudulently disregarded federal law concerning the sale of Subsy to Linden Care and to hide the enormous sales volume and suspicious activity concerning Subsys sales to Linden Care, solely in the



interests of profit.

25. Doud and RDC intentionally ignored federal law and put the health of the general public in grave danger, including Sarah Fuller, for their own financial benefit.
26. Drug distributors such as RDC serve as a major source of checks and balances within the system of controlled dangerous substances.
27. Orders for controlled dangerous substances go through wholesale distributors such as RDC and distributors are required by law to report suspicious orders to the DEA.
28. At all times relevant hereto RDC was fully aware that the sales of Subsys to Linden Care were suspicious orders, illegitimate and unlawful and knowingly hid the information from the DEA.
29. On April 23, 2019 Doud was charged in the United States District Court for the Southern District of New York with conspiracy to traffic narcotics. The indictment sets forth the specific allegations that Doud and RDC were knowingly dispensing drugs to individuals who had no legitimate need for them. Paragraph 16 of the indictment specifically identifies “Pharmacy 1” as one of the nation’s largest dispensers of Subsy and indicates Doud and RDC intentionally and knowingly distributed huge amounts of Subsys to “Pharmacy 1” knowing they were being diverted for illegitimate purposes. “Pharmacy 1” is Linden Care.
30. A three count criminal information charging RDC with conspiracy to distribute controlled substances outside the scope of professional practice and not for a legitimate medical purpose has been entered in the United States District Court for the Southern District of New York by consent decree. (See United States of America v. Rochester

Drug Co-Operative, Inc. criminal information attached hereto as Ex. E) Plaintiffs hereby incorporate the factual allegations and evidence cited in Exhibit “E” as part of this complaint as though specifically set forth herein.

31. RDC has entered into Deferred Prosecution Agreement with the U.S. Department of Justice stipulating to the facts as set forth in Ex. “E” and has accepted and acknowledged that they are guilty of and responsible for distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose. (See attached Ex. F) Plaintiffs hereby incorporate the factual allegations and evidence cited in Exhibit “F” as part of this complaint as though specifically set forth herein. William Pietruszewski, (“Pietruszewski”) Chief Compliance Officer of RDC, has been charged with, inter alia, conspiracy to distribute narcotics under a sealed information. Pietruszewski has admitted his responsibility in the criminal scheme and has entered into a guilty plea and cooperation agreement. (See Ex. G) Plaintiffs hereby incorporate the factual allegations and evidence cited in Ex. G as though specifically set forth herein.
32. Linden Care dispensed Subsys to Sarah Fuller from January 7, 2015 until her death on March 25, 2016, corresponding directly with the dates RDC has admitted they were illegally distributing Subsys to Linden Care to be unlawfully distributed to patients not for a legitimate medical purpose.
33. As a direct and proximate result of the actions of RDC a large volume of deadly Subsys was wrongfully dispensed to Sarah Fuller resulting in the addiction, serious personal injury and death of Sarah Fuller as set forth more fully herein.

#### **FACTUAL CHRONOLOGY**



34. 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.
35. 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.
36. 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.
37. 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.

38. As more fully discussed herein, Defendants, Insys, Kapoor, Babich, Burlakoff and RDC 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 solely for their own financial benefit. They have done this in Sarah Fuller's case and have done so regularly and systematically across the country
39. 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 prescriptions for Subsys.
40. Kapoor is a pharmaceutical entrepreneur who is well known in the pharmaceutical industry for applying aggressive marketing tactics to increase sales. Kapoor personally directed, oversaw and managed the fraudulent scheme of Insys by and through, among other things, his participation in daily "update" conference calls with indicted high level executives, receiving daily "JK" emails, weekly "JK" tracking reports, as well as being copied and blind carbon copied on innumerable emails and correspondence specifically describing the ongoing fraudulent scheme as specifically set forth in Exhibit "B" and



Exhibit “C.”

41. In 2007 Kapoor hired Babich as CEO of Insys. Babich was a wealth management executive with little pharmaceutical experience,. Babich in turn hired Burlakoff, who had previously worked for Cephalon, a competitor of Insys and the manufacturer of “Actiq,” a similar Fentanyl drug approved solely for end of life cancer patients. Burlakoff was experienced in marketing Fentanyl for off label purposes from his time at Cephalon. In September of 2012, three months after being hired, Burlakoff was promoted to Vice President of Sales for Insys.
42. Since the approval of Subsys in 2012, Insys, Kapoor, Babich, Burlakoff and RDC have 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.
43. 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.
44. Insys, Kapoor, Babich, Burlakoff, and RDC blatantly disregarded this basic requirement as a drug manufacturer and dispenser 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, Kapoor, Babich, Burlakoff and RDC infiltrated the medical community with lies, misinformation, kickbacks and financial rewards which led to a large span of the medical community in the State of New Jersey to prescribe Subsys for off-label indications for which there was no proven safe use.

45. Subsys is a very expensive drug for which there was great financial benefit for the defendants 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.
46. 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.
47. Insys, through the deliberate unlawful actions of Kapoor, Babich, Burlakoff and RDC achieved rapid growth through a multitude of false, fraudulent and misleading tactics. The Defendants Insys, Kapoor, Babich and Burlakoff, 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.

48. Throughout its various market territories, Insys, Kapoor, Babich and Burlakoff 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.
49. 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 drug, Insys, Kapoor, Babich and Burlakoff developed and implemented the “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.
50. In addition to targeting prescribers, Insys, Kapoor, Babich and Burlakoff specifically instructed their 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.



51. 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.
52. The Defendants earned more money when a higher dose was prescribed, as did Insys sales representatives, whose compensation was based largely on commission. Subsys sales representatives were given an economic incentive to recommend a higher dose that is contrary to the FDA guidelines and the terms of the TIRF-REMS program. Insys, Kapoor, Babich and Burlakoff developed a compensation plan that promoted, encouraged and rewarded their schemes of fraud by aligning sales staffs' bonus to the strength of Subsys they could fraudulently induce physicians to prescribe.
53. Insys, Kapoor, Babich and Burlakoff 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.
54. 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.

55. 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, Kapoor, Babich and Burlakoff set up an entire department at Insys 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 prior authorization for Subsys (prior authorization is a requirement by health insurers to **physicians** to justify why a certain drug may be needed for a patient) and then ultimate payment through fraudulent inducement from insurers for Subsys prescribed for indications for which it was not approved nor safe.
56. Insys, Kapoor, Babich and Burlakoff 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 to fraudulently induce the granting of prior authorization and ultimate payment for Subsys. Insys, Kapoor, Babich and Burlakoff set up IRC working groups with high level Insys executives, including themselves, to

monitor the IRC schemes they had planned and had executed to do whatever was needed to succeed in duping insurers and PBMs into granting and paying for Subsys for those it knew it was not approved nor safe.

57. Insys, Kapoor, Babich and Burlakoff 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.
58. If Insys' IRC unit was unable to gain approval upon its first submission of the Prior Authorization for Subsys, Insys, Kapoor, Babich and Burlakoff 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.
59. Insys, Kapoor, Babich and Burlakoff were successful with their 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, Kapoor, Babich and Burlakoff needed a pharmacy and a wholesale distributor to turn a blind eye to what it was doing and dispense Subsys throughout the country and Insys' main partners to execute its scheme during the years 2012-2016 were Linden Care and RDC.
60. 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.

61. 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.
62. 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.
63. 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.
64. The systematic scheme and fraud of Insys, Kapoor, Babich, Burlakoff, Linden Care, RDC, Doud and Dr. Matalon recklessly, wantonly and negligently disregarded the duty of care owed to Sarah Fuller by engaging in practices that allowed dangerous amounts and combinations of schedule II and schedule IV narcotics, along with Subsys, to be prescribed and delivered without any medical justification which caused Sarah to become addicted which then led slowly and painfully to her death.
65. 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 health. However, Sarah Fuller did not have cancer nor pain from cancer.

66. 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.
67. 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.
68. 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.
69. 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-Issac Spalter, a sales representative employed by Insys and herself for the purpose of allowing the Ms. Isaac Spalter to convince 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 as she had been trained to do by Kapoor, Babich and Burlakoff. 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.

70. 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.
71. 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.
72. Linden care was only able to carry out its part in the scheme due to the actions of the Defendant RDC in fraudulently, negligently and willfully hiding the suspicious prescriptions and activities of Linden Care and other actors in the scheme from being



reported to the DEA contrary to federal law. RDC distributed Subsys to Linden Care knowing it was being dispensed to patients like Sarah Fuller for illegitimate and illegal purposes.

73. The fraudulent sales and other practices as described were how Insys operated companywide and across the country as planned by and promoted by the Defendants named herein.
74. On January 7, 2015, as Insys employee from the "IRC", Jeanne Flores, called Sarah Fullers' Medicare PBM, Envision Rx, from the Insys headquarters in Chandler, Arizona. The Insys representative, as she had been trained to do under the direction of Kapoor, Babich and Burlakoff identified herself as being a member of Dr. Matalon's staff and fraudulently advised Envision, among other things, that Sarah Fuller needed to use Subsys because she had cancer and was suffering from breakthrough cancer pain. The call was blocked so Envision could not tell that the call was coming from Insys headquarters in Arizona but the phone record since obtained shows the call was made from Insys headquarters just as hundreds of these fraudulent phone calls were being made each day as part of Insys companywide fraudulent schemes. As part of its regular course of business, Envision RX recorded incoming calls for prior authorization of drugs and the fraudulent phone call made by Ms. Flores is in the possession of Envision, Insys and Plaintiff.

75. Twenty days later, on January 26, 2015, without any explanation and medical justification, upon the urging of the Insys sales representative, as she had been trained to do by Kapoor, Babich and Burlakoff 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. On or around this date, a second fraudulent phone call almost identical to the first was made by Insys IRC employee, Jeanna Flores, to Envision RX seeking a new prior authorization for the increase of Subsys to 600 mcgs. All the same fraudulent pretenses were utilized by Ms. Flores as she had been trained, coached and instructed by Insys, Kapoor, Babich and Burlakoff. This second call was also recorded by Envision RX as part of its regular course of business.
76. Linden Care and RDC, Insys' partners in executing its fraudulent schemes in dispensing Subsys to those it was not intended and in dosages that were deadly, 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. Linden Care needed a wholesale drug distributor as a partner in order to carry out their illegal scheme and could not have delivered the Subsys to Sarah Fuller without the knowing and active participation and cooperation of RDC.
77. Defendant RDC was Linden Care's partner in executing the illegal, fraudulent and dangerous scheme by hiding the suspicious activity of Linden Care from the DEA and ensuring that the dangerous deliveries of Subsys would be delivered to Sarah Fuller.

78. 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. This activity continued unabated from January of 2015 up until the time of Sarah's death on March 25, 2016 as a direct result of the actions of RDC and Doud in hiding the suspicious and illegal activity from the DEA and continually dispensing Subsys to Linden Care knowing it was being dispensed by Linden Care for illegal and illegitimate purposes.
79. On March 25, 2016, Sarah Fuller died due to an adverse reaction to prescription medications, namely fentanyl (Subsys), filled and dispensed by Linden Care and RDC.

**FIRST 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. Defendants Insys Therapeutics, Inc., John Kapoor, Michael Babich, and Alec Burlakoff**

80. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.
81. 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.
82. 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:31-1 through 6.

83. The actions of the Defendants, Insys, John Kapoor, Michael Babich, and Alec Burlakoff 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.
84. 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 Defendants, jointly, severally and/or individually, and/or by their agents, servants, and employees.
85. The liability of the Defendants is predicated upon individual acts and/or on principles of respondeat superior and the Defendants are liable individually, jointly, severally and/or in the alternative.
86. 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 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) instructing and training employees to mislead and deceive insurers regarding their employment, patient diagnoses and tried and failed medications;
- (o) calling Sarah Fullers' insurer and misrepresented that they were calling from the office of the Decedent's doctor and giving false information regarding the Decedent's diagnosis and tolerance to opioids in order to fraudulently obtain approval for the drug.
- (p) negligence/recklessness/wantonness as a matter of law.



87. 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., John Kapoor, Michael Babich, and Alec Burlakoff, 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, and Deborah Fuller and David Fuller, individually v. Defendants Insys Therapeutics, Inc., John Kapoor, Michael Babich and Alec Burlakoff**

88. Plaintiffs incorporate the previous paragraphs at length in this count as fully set forth herein at length.

89. 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.

90. 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:31-1 through 6.

91. The actions of the Defendants, Insys, John Kapoor, Michael Babich, and Alec Burlakoff, 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.
92. 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 the Defendants, jointly, severally and/or individually, and/or by their agents, servants, and employees.
93. The liability of the Defendants is predicated upon individual acts and/or on principles of respondeat superior and the Defendants are liable individually, jointly, severally and/or in the alternative.
94. 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 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) instructing and training employees to mislead and deceive insurers regarding their employment, patient diagnoses and tried and failed medications;
- (o) calling Sarah Fullers’ insurer and misrepresented that they were calling from the office of the Decedent’s doctor and giving false information regarding the Decedent’s diagnosis and tolerance to opioids in order to