

Next Generation Compliance: Using Analytics to Reduce Compliance Risks

Mohammad Ovais

Agenda

- Implications of Transparency
 - Case of Insys Therapeutics
- Using Data Analytics to highlight risk areas

Implications of Transparency

- ***Penalties for What is Not Reported***
 - \$1,000-\$10,000/transaction up to \$150,000
 - \$10,000-\$100,000/transaction up to \$1 million
- ***Penalties for What **Is** Reported***
 - Kickbacks
 - False Claims

Case Study: Insys Therapeutics

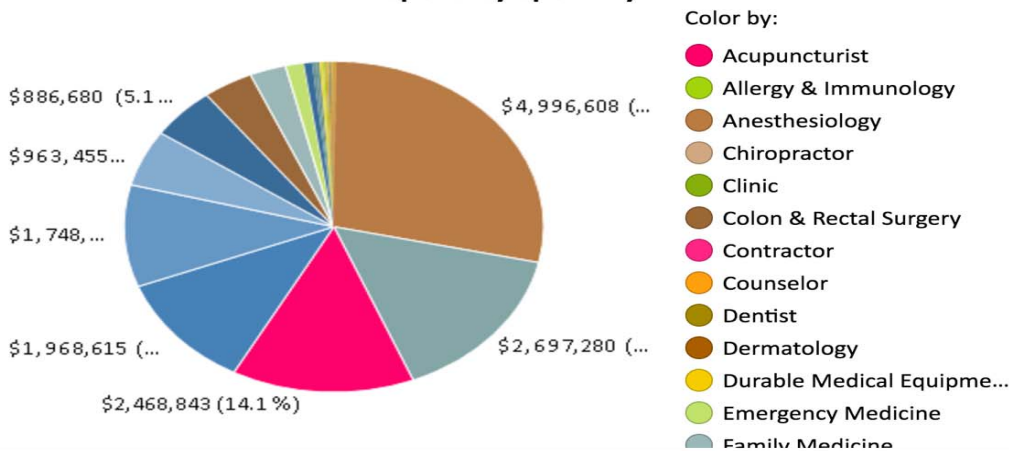
- Launched Subsys in March 2012
- Sublingual Fentanyl Spray for Breakthrough Cancer Pain
 - Sudden, temporary flares of severe pain
- Black box Warning and Subject to Risk Evaluation and Mitigation Strategy (REMS)

First incident where prosecutors have used Open Payments data in conjunction with Medicare Part D data

Therapeutics

Year	Total Spend	Physician Spend	Teaching Hospital Spend	No. of Physicians	No. of Teaching Hospitals
2013	\$2,834,528	\$2,775,946	\$37,020	1,969	1
2014	\$8,234,873	\$7,512,404		4,101	0
2015	\$6,480,291	\$6,297,978	\$152,988	7,781	2
Grand total	\$17,549,692	\$16,586,328	\$190,008	10,683	3

Spend by Specialty



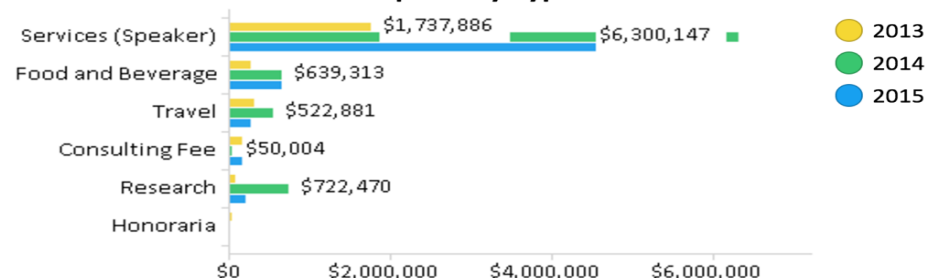
Spend by Physician

Physician	Specialty	State	Spend
JEFFREY H KESTEN	Physical Medi...	CO	\$294,038
GORDON MATTHEW FREEDMAN	Anesthesiology	NY	\$283,022
STEVEN YOUNGHAN CHUN	Anesthesiology	FL	\$269,963
FADI SAMIR BRAITEH	Internal Medi...	NV	\$235,746
STEVE FANTO	Pain Medicine	AZ	\$234,463
NIKESH DILIP SETH	Anesthesiology	AZ	\$230,551
BART GERARD GATZ	Anesthesiology	FL	\$229,068
STEVEN MICHAEL SIMON	Physical Medi...	KS	\$221,423
JEFFREY LAWRENCE GOLDSTEIN	Emergency M...	NY	\$215,493
AATHIRAYEN THIYAGARAJAH	Specialist	SC	\$201,993
ALEXANDER EUGENE WEINGAR...	Pain Medicine	NY	\$200,536
RANDALL ALAN SCHARLACH	Radiology	CA	\$188,145
CHRISTOPHER WERNER INCE	Anesthesiology	TX	\$179,017

Spend by Teaching Hospital

Teaching Hospital	Spend
UT MD ANDERSON CANCER CENTER	\$149,988
LOYOLA UNIVERSITY MEDICAL CENTER	\$37,020
HENRY FORD HOSPITAL	\$3,000

Spend by Type



Case Study: Insys Therapeutics

19
20
21 Derick Larson
22
23 v.
24 Insys The
25
26
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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Lead Case No. CV-14-01043-GMS
Consolidated with:
CV-14-1077-PHX-GMS

3 119. Attached Exhibit D is a spreadsheet containing a list of payments from
4 Insys to various physicians during the five month period from August 2013 through
5 December 2013 recently obtained under the ACA's Sunshine Act. Although food and
6 beverages comprised the largest number of payments, the total dollar value of payments
7 identified as "Food and Beverage" was only \$200,502.12. The most significant amounts of
8 money, to wit, \$750 or more, were paid to 170 doctors for "compensation for services other
9 than consulting, including serving as faculty or as a speaker at a venue other than a
10 continuing education program," "honoraria," and "consulting fees." From the records Lead

Case Study: Insys Therapeutics

19		UNITED STATES DISTRICT COURT	
20		DISTRICT OF ARIZONA	
21 Derick Larsen		No. CV-14-01043-GMS	
22		20	continuing education program,” “honoraria,” and “consulting fees.” From the records Lead
23 v.		21	Plaintiff was able to access, [REDACTED] appears to have paid a total of \$2,157,162.49 to these
24 Insys Therapeutics		22	doctors in just a single five-month period. Payments to the 170 doctors, identified as speaker
25		23	fees, consulting fees, honoraria, or travel and lodging, are set forth in Exh. D. [REDACTED]
26		24	were paid tens of thousands of dollars. Of course, net revenues for Subsys sales for the
27		25	second half of 2013 were \$67.6 million. As CEO Babich explained during the Q1’14
		26	conference call, [REDACTED] only 120 physicians write 20% of all TIDE prescriptions. Defendant
		27	[REDACTED] appears to have targeted these doctors and rewarded them generously for writing Subsys
			prescriptions.

Case Study: Insys Therapeutics

EXHIBIT D

UNITED STATES DISTRICT COURT
OF ARIZONA

INFORMATION OBTAINED UNDER THE SUNSHINE ACT PROVISIONS OF THE AFFORDABLE CARE ACT
OF PAYMENTS MADE TO PHYSICIANS RELATING TO THE SALES AND MARKETING OF SUBSYS,
AS REPORTED BY INSYS FOR THE PERIOD AUG. 1, 2013 THROUGH DEC. 31, 2013

20
21 Derick La
22
23 v.
24 Insys T
25
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GRAND TOTAL OF ALL PAYMENTS TO ALL PHYSICIANS REPORTED FOR THE PERIOD AUGUST 2013 THROUGH DECEMBER 2013 \$2,357,664.61

GRAND TOTAL OF PAYMENTS TO ALL PHYSICIANS REPORTED FOR THE PERIOD AUGUST 2013 THROUGH DECEMBER 2013 (EXCLUDING FOOD AND BEVERAGES) \$2,157,162.49

GRAND TOTAL OF PAYMENTS TO ALL PHYSICIANS FOR SPEAKER FEES OR CONSULTING FEES (INCLUDING TRAVEL AND LODGING, BUT NOT FOOD AND BEVERAGES) \$468,205.47

GRAND TOTAL OF PAYMENTS TO ALL PHYSICIANS FOR SPEAKER FEES OR CONSULTING FEES (INCLUDING TRAVEL AND LODGING, BUT NOT FOOD AND BEVERAGES) \$1,688,957.02

TOTAL VALUE OF FOOD AND BEVERAGE PAYMENTS TO ALL PHYSICIANS, NOT LIMITED TO THOSE IN RECEIPT OF SPEAKER FEES OR CONSULTING FEES \$200,502.12

Data Retrieved From the Open Payments Site on October 14, 2014

Case Study: Insys Therapeutics

19

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14 Derick Larson,
15 Plaintiff,
16 v.
17 Insys Therapeutics Incorporated,
18 Defendants.

19

20 Hongwei Li,
21 Lead Plaintiff,
22 v.
23 Insys Therapeutics Incorporated,
24 Defendants.

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Derick Larson,
Plaintiff,
v.
Insys Therapeutics Incorporated, et al.,
Defendants.

Hongwei Li,
Lead Plaintiff,
v.
Insys Therapeutics Incorporated, et al.,
Defendants.

Lead Case No. CV-14-01043-GMS
Consolidated with:
No. CV-14-01077-GMS

**SUMMARY NOTICE OF PENDENCY
AND PROPOSED SETTLEMENT OF
CLASS ACTION**

TO: ALL PERSONS WHO PURCHASED PUBLICLY TRADED SHARES OF INSYS THERAPEUTICS, INC. COMMON STOCK BETWEEN NOVEMBER 12, 2013, AND MAY 14, 2014, INCLUSIVE, AND INCURRED DAMAGES (THE "CLASS").

YOU ARE HEREBY NOTIFIED that a settlement, in the amount of [REDACTED] of common stock, and [REDACTED] is [REDACTED]. A hearing will be held before the Honorable G. Murray Snow in the United States District Court for the District of Arizona, 401 West Washington Street, Phoenix, AZ 85003, at 9:00 a.m. on December 4, 2015, to determine: (i) whether the Settlement and Plan of Allocation should be approved by the Court as fair, reasonable, adequate, and in the best interests of the Settlement Class; (ii) whether Lead Counsel's application for an award of attorneys' fees (of not more than 30% of the Settlement Fund) and reimbursement of expenses (of not more than \$75,000) should be approved; (iii) whether the Court should grant the Lead Plaintiff's reimbursement (of not more than \$2,500) for his reasonable costs and expenses (including lost wages) directly related to his representation of the Settlement Class; and (iv) whether the Court should approve the release of Released Claims and the Released Defendants' Claims against any and all Released Persons and dismiss the Action with prejudice.

Case Study: Insys Therapeutics

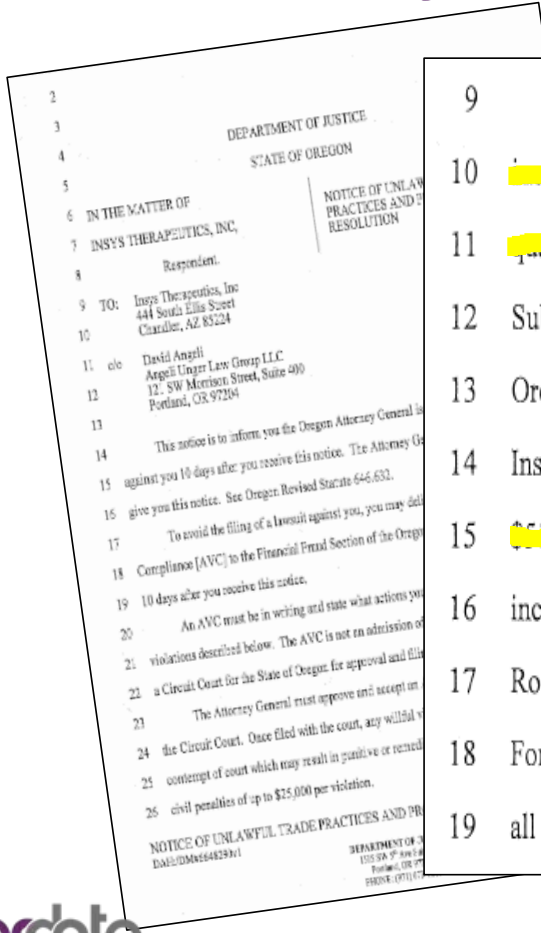
OREGON DEPARTMENT OF JUSTICE

AG Rosenblum Settles with Pharmaceutical Company Insys over Unlawful Promotion of the Powerful Opioid Subsys®

August 5, 2015

Oregon Attorney General Ellen Rosenblum today reached a \$4.4 million settlement with Insys, the company that manufactures the schedule II opioid drug Subsys, to resolve allegations that the powerful drug approved by the Food and Drug Administration (FDA) to treat cancer pain was marketed in Oregon for off-label uses such as non-cancer neck and back pain. The Assurance of Voluntary Compliance (AVC) also resolved allegations that the company provided improper financial incentives to some doctors to increase Subsys prescriptions, targeted doctors for aggressive promotion of Subsys when the doctor was not qualified to prescribe the drug, and deceptively promoted Subsys for treatment of mild pain. Oregon is the first government entity to settle with Insys for this alleged misconduct.

Case Study: Insys Therapeutics



9 Through its payments to Gallant and Rosenblum, Insys unreasonably sought to
10 [redacted] prescriptions which for Subsys. Gallant [redacted] speaker not because he was
11 [redacted] qualified to speak to doctors about Subsys — he was not [redacted] him to prescrib
12 Subsys. Nonetheless, Insys deceptively held Gallant out as a qualified speaker and sought out
13 Oregon physicians to attend his talks. Although Gallant's prescribing of Subsys failed to meet
14 Insys' expectations, Gallant was the top prescriber of Subsys in Oregon. Out of the total of
15 \$511,888 worth of Subsys in Oregon, Gallant wrote prescriptions worth \$250,000,
16 including \$95,800 paid by the Public Employee Benefits Board (PEBB). In 2013, Gallant and
17 Rosenblum were responsible for approximately 80% of all Subsys prescriptions filled in Oregon.
18 For the years 2012 and 2013, Gallant, Rosenblum, and Blackburn were responsible for 78% of
19 all Oregon Subsys prescriptions.

Case Study: Insys Therapeutics

July 14, 2015

UNCATEGORIZED

The Black World of Insys Therapeutics

By Roddy Boyd

Slowly but surely answers to the many riddles of how Insys Therapeutics could achieve its mercurial success are beginning to emerge.

<http://sirf-online.org/2015/07/14/the-darkening-world-of-insys-therapeutics/>

The pharmaceutical company has only one commercial offering, but its sales growth has managed to reach \$1 billion.

The Southern Investigative Reporting Foundation, via a database tracking TIRF-REMS prescriptions, identified 60 Subsys prescriptions that Freedman wrote from March 2012 (when Insys obtained FDA approval to sell the drug) to the end of December 2013.

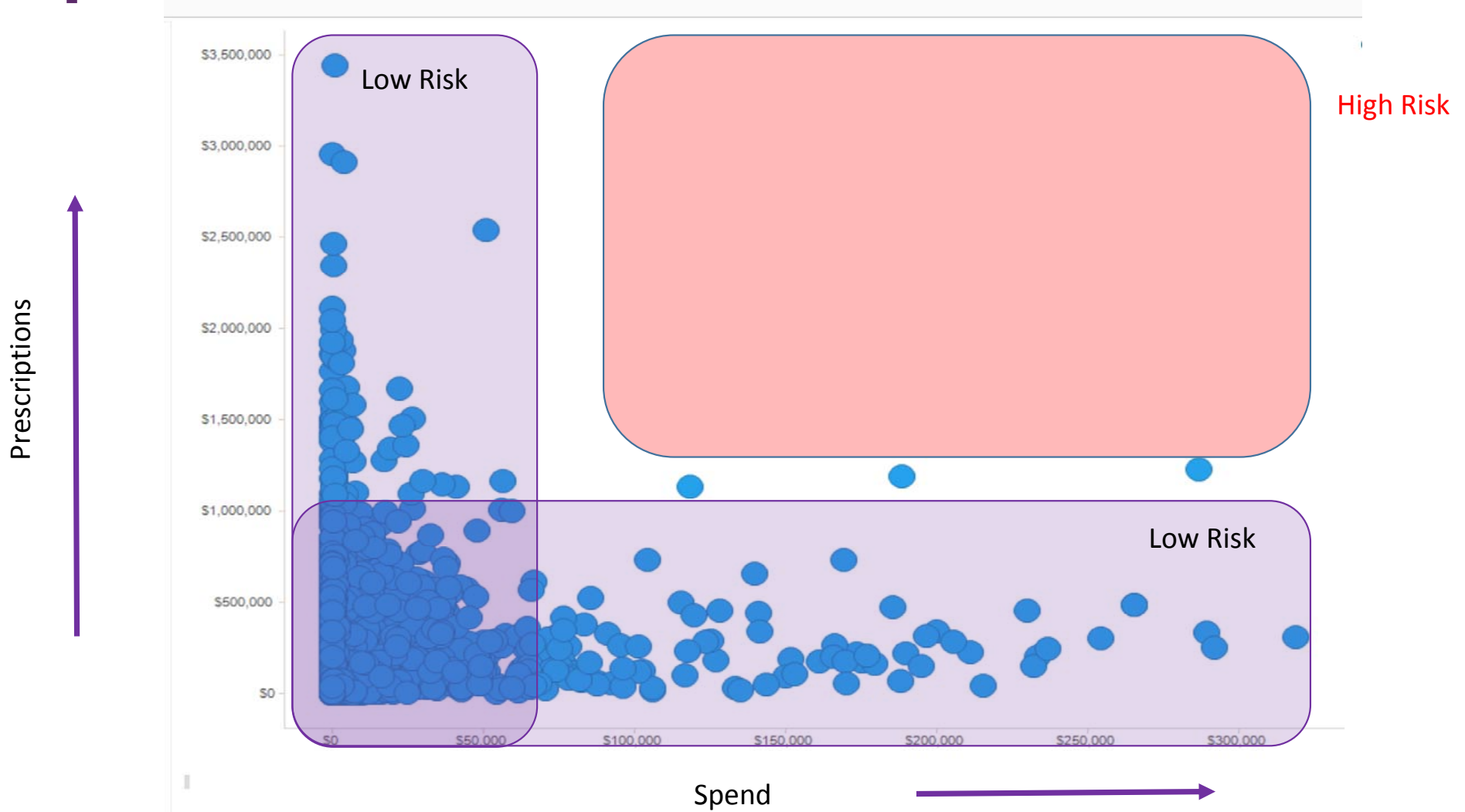
Therein lies the rub.

Case Study: Insys Therapeutics

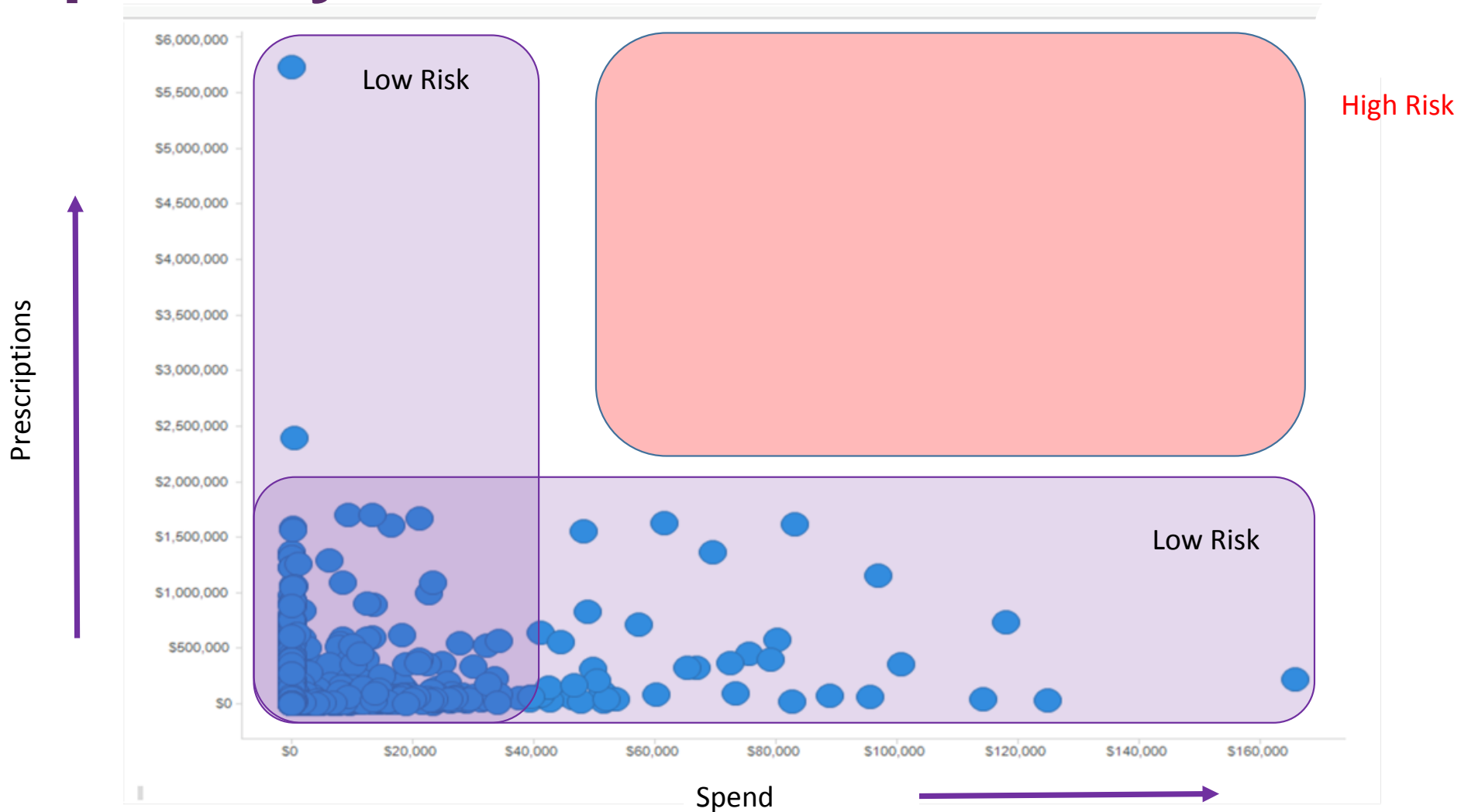
Doctor	Insys Speaker Fees	Total Paid	2013 Total	2013 and 2014 Total	Rank in Dollar Amount of 2013 Medicare Prescriptions of Subsys
[REDACTED]	\$147,345	\$148,888	\$45,485	\$193,405	12
Steven Chun	\$141,750	\$147,996	\$45,322	\$193,318	12
Jeffrey Kesten	\$114,945	\$122,317	\$67,130	\$189,447	17
Bart Gatz	\$113,195	\$117,181	\$37,026	\$154,207	6
Jeffrey Goldstein	\$112,340	\$121,378	\$27,582	\$148,960	20
Fadi Braiteh	\$106,943	\$119,883	\$28,225	\$148,108	N/A
Aathirayen Thiyagarajah	\$105,190	\$114,869	\$12,493	\$127,362	N/A
Nikesh Seth	\$105,188	\$114,421	\$27	\$114,448	N/A
Alexander Weingarten	\$102,540	\$109,195	\$21,822	\$131,017	10
Xiulu Ruan	\$100,140	\$103,037	\$41,914	\$144,951	5
Steven Simon	\$97,320	\$103,660	\$47,314	\$150,974	27
Mahmood Ahmad	\$89,438	\$102,865	\$8,559	\$111,424	N/A
Fernando Avila	\$88,940	\$94,214	\$19,778	\$113,992	N/A

(In the chart, Medicare rank is determined by the value of Subsys prescriptions written by the doctors.)

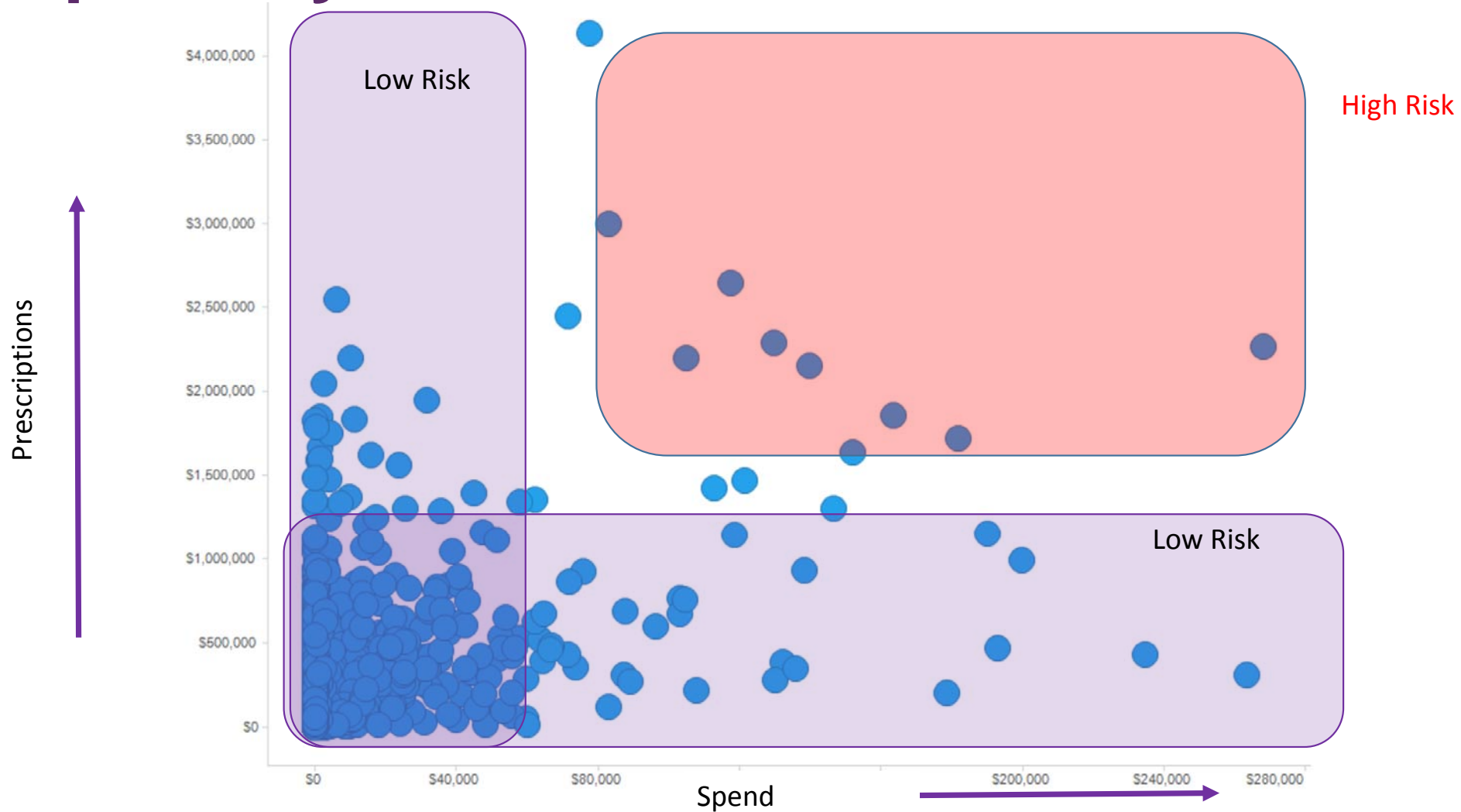
Open Payments with Med Part D



Open Payments with Med Part D



Open Payments with Med Part D

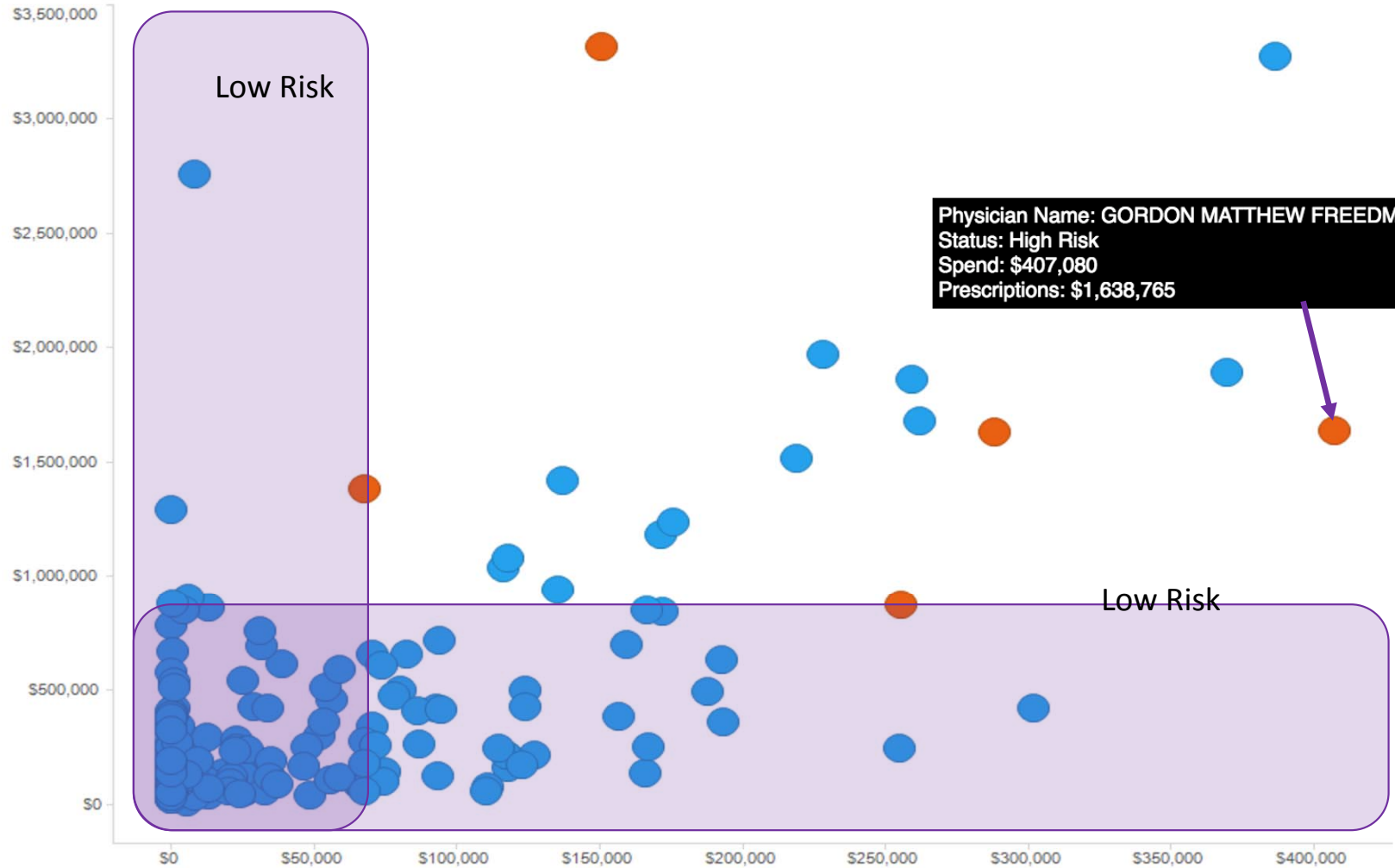


Insys Therapeutics

Select Company

(All) 215 values

INSYS THERAPEUTICS INC



Dr Gordon Freedman – Speaker

Programs

Page

Search Company:

insys

Select Company:

INSYS THERAPEUTICS INC

Exclude Txn under:

100

Year:

- 2013
- 2014
- 2015

Types of Payment:

Type to search in list

- (All) 17 values
- Charity
- Consulting Fee
- Education
- Entertainment
- Food and Beverage
- Gift

Physician Details

Physician	Specialty	Types of Payment	INSYS THERAPEUTICS INC Spend	INSYS THERAPEUTICS INC Avg. Spend	Industry Spend	Industry Avg. Spend
GOPALA KRISHNA DWARAKANATH	Anesthesiology, ...	Education, Food ...	\$162	\$3	\$1,013	\$17
GORDON LOUIS GRADO	General Practice,...	Education, Food ...	\$104	\$2	\$2,221	\$39
GORDON MARC NOVAK	Anesthesiology	Food and Beverage	\$114	\$3	\$701	\$18
GORDON MATTHEW FREEDMAN	Anesthesiology, ...	Consulting Fee, ...	\$283,022	\$450	\$8,117	\$13
GORGUN AKPEK	Internal Medicine	Consulting Fee, ...	\$104	\$1	\$22,458	\$299
GRACE I FORDE	Anesthesiology, ...	Consulting Fee, ...	\$6,015	\$17	\$62,567	\$180
GRACE LOPEZ	Anesthesiology	Food and Beverage	\$101	\$5	\$250	\$13
GRAY ROWEN SWOR	Radiology	Food and Beverage	\$158	\$76	\$352	\$59

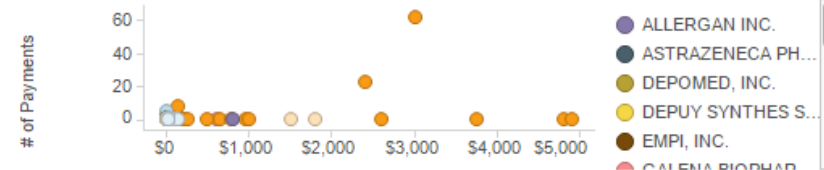
Industry's Speaker Program Details

Company	Transactions	Total Spend	Avg Spend	Min. Spend	Max. Spend
INSYS THERAPEUTICS INC	431	\$283,022	\$657	\$1	\$4,900
TEVA PHARMACEUTICALS USA, INC.	64	\$4,166	\$65	\$1	\$1,800
PURDUE TRANSDERMAL TECHNOLOGIES L.P.	1	\$800	\$800	\$800	\$800
DEPOMED, INC.	36	\$778	\$22	\$1	\$144
GALENA BIOPHARMA, INC.	4	\$768	\$192	\$24	\$600
PURDUE PHARMA L.P.	19	\$279	\$15	\$1	\$22
XENOPORT INC.	13	\$253	\$19	\$14	\$24
VERTICAL PHARMACEUTICALS, LLC	2	\$241	\$120	\$111	\$129

Transaction Details

Company Name	Payment Date	Spend
GALENA BIOPHARMA, INC.	1/16/2014	\$103
GALENA BIOPHARMA, INC.	10/23/2013	\$41
JANSSEN PHARMACEUTICALS, INC	12/23/2013	\$25
JANSSEN PHARMACEUTICALS, INC	10/25/2013	\$19
GALENA BIOPHARMA, INC.	8/20/2015	\$24

Spend per Selected Physician



Dr Gordon Freedman (spend vs

Medicare

Details

Physician Name

GORDON MATTHEW FREEDMAN

Physician Specialty

Allopathic & Osteopathic
Physicians/Anesthesiology/Pain Medicine

Total Drug Cost

\$2,678,273

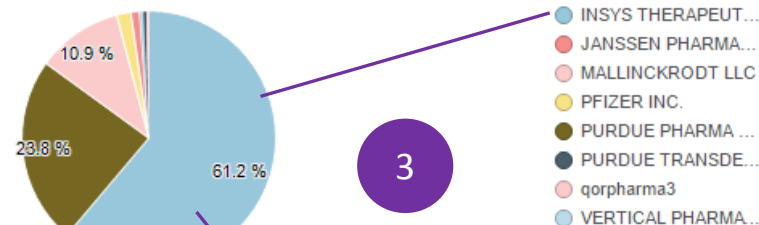
Total Spend

\$291,139

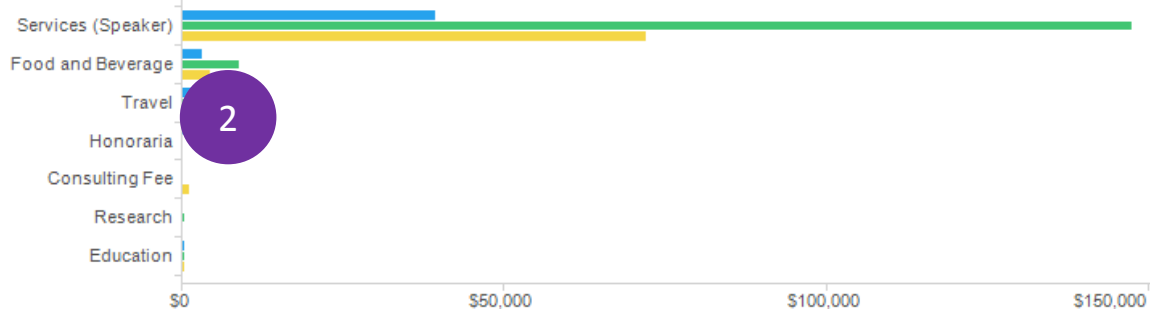
Total Spend by Manufacturers



Total Prescription Amount



Spend by Nature of Payment



Spend by Drugs

Drug Name	Spend	Prescription Amo...	Total Claims
Subsys	\$407,080	\$1,638,765	104
FENTORA	\$3,544	\$292,666	13
BUTRANS	\$1,762	\$19,856	82
Nucynta	\$302	\$28,783	112
Lorzone	\$258	\$12,869	29
OXYCONTIN	\$162	\$627,536	739
CELEBREX	\$70	\$17,712	59
Exalgo	\$50	\$9,045	12
LYRICA	\$38	\$31,041	98

Case Study: Insys Therapeutics

Doctors Last Name	Doctors First Name	City	State	Total Number of Prescriptions	Total paid
Ruan	Xiulu	MOBILE	AL	333	\$1,813,142.62
Couch	John	MOBILE	AL	116	\$1,002,658.71
Balfour	Glenn	OCEANSIDE	CA	52	\$829,569.26
Grote	Stewart	LANSING	KS	39	\$671,890.28
Khanna	Parveen	MIDDLEBURG	FL	94	\$598,596.64
Grant SR.	Paul	FORT WORTH	TX	55	\$384,750.12
Clough	Christopher	SOMERSWORTH	NH	14	\$321,211.74
Somerville	Judson	LAREDO	TX	19	\$316,799.63
Caudill	Jeffrey	JACKSONVILLE	FL	49	\$298,605.04
Wu	Shawn	GULFPORT	MS	89	\$270,300.08
Wand	Paul	PEMBROKE PINES	FL	36	\$255,805.37
Milnor III	John	MEMPHIS	TN	26	\$245,670.87
Kornick	Craig	JACKSONVILLE	FL	33	\$234,223.58
Lee	Tse	DAYTONA BEACH	FL	48	\$225,875.15
Fanto	Steve	SCOTTSDALE	AZ	18	\$212,751.28

TRICARE
Prescriptions
1/1/13-5/31/14

Former Insys sales manager Natalie Reed Perhacs recently pleaded guilty to conspiracy to commit health care fraud including engaging in kickback schemes in the United States District Court for the Southern District of Alabama (Southern Division).

Insys was the subject of a CNBC investigation in November which revealed that two physicians in Mobile, Alabama, Dr. Xiulu Ruan and Dr. John Couch, partners at a practice, received over \$210,000 from Insys Therapeutics in 2013 and 2014 for things like speaking fees, travel and meals.



A drug stock skyrocketing from painkiller profits

The company's main revenue generating drug is a highly addictive opiate 100 times more powerful than morphine, called Subsyst Fentanyl.

In May 2015, Drs. Ruan and Couch were arrested on drug and fraud charges and both pleaded not guilty.

The agreement with the Insys sales rep, [filed on Feb. 17 and obtained by CNBC](#), states that Perhacs was hired by Insys as a kickback to Dr. Ruan, who became fond of her and "went out of his way" to try to get her hired as a sales representative with a pharmaceutical company.



Top Prescribers of Subsyst

The following lists the top prescribers nationally of the cancer pain drug, Subsyst, marketed by Insys Therapeutics, in the Medicare program in 2013, and the compensation they received for speaking engagements, food and travel from Insys from Aug 2013- Dec 2014:

	Prescriptions written	Payments from Insys
Dr. Gavin Awerbuch (MI)	1,161	\$ 89,892
Dr. Xiulu Ruan (AL)	158	\$ 144,000
Dr. John Couch (AL)	122	\$ 75,429
Dr. Jerrold Rosenberg (RI)	103	\$ 128,000
Dr. Steve Fanto (AZ)	77	\$ 130,000
Dr. Bart Gatz (FL)	77	\$ 154,000
Dr. Judson Somerville (TX)	71	\$ 67,463
*Heather Alfonso, APRN (CT)	69	\$ 83,000

*Alfonso's time period: January 2013-March 2015

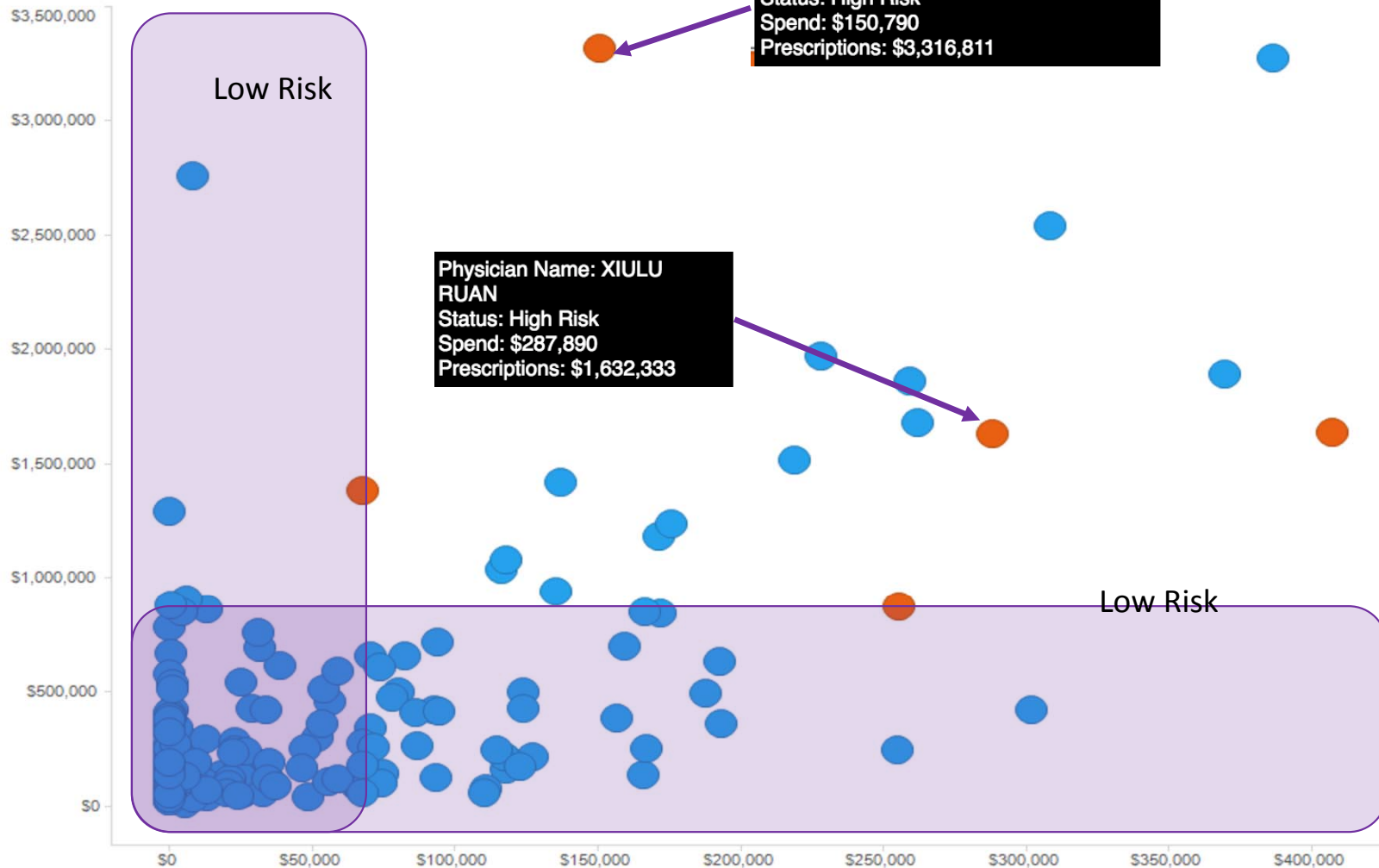
Sources: Centers for Medicare & Medicaid Services; ProPublica

Insys Therapeutics

Select Company

(All) 215 values

INSYS THERAPEUTICS INC



Dr John Couch – Speaker Programs

Home Physician Details

Select Year

- 2013
- 2014
- 2015

Speaker Programs

42

Total Speaker Program Spend

\$84,590

Avg Speaker Program Spend

\$1,994.05

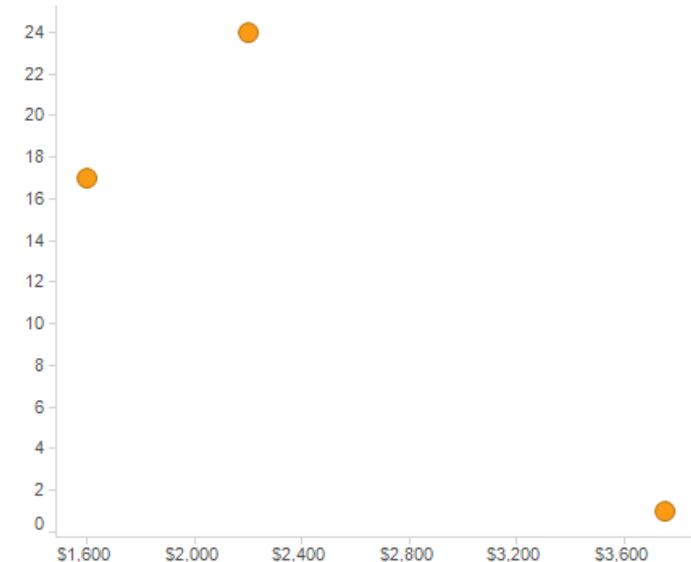
Speaker Details

Physicians	Specialty	Speaker Programs	Total SP Spend	Avg SP Spend	Min SP Spend	Max SP Spend
ROGER ASHLEY KASENDORF	Allopathic & Osteopathic Physicians/Physical Medicin...	46	\$107,940	\$2,347	\$390	\$3,750
TODD RUSSELL SCHLIFSTEIN	Allopathic & Osteopathic Physicians/Physical Medicin...	45	\$131,345	\$2,919	\$495	\$4,700
HOWARD MARK COHEN	Allopathic & Osteopathic Physicians/Psychiatry & Ne...	43	\$87,390	\$2,032	\$390	\$4,100
JERRY WAYNE LEWIS	Allopathic & Osteopathic Physicians/Anesthesiology/...	42	\$80,700	\$1,921	\$950	\$3,750
JOHN PATRICK COUCH	Other Service Providers/ Specialist	42	\$83,750	\$1,994	\$1,600	\$3,750

Industry Speaker Program Spend

Company	Speaker Program	Total SP Spend	Avg ...	Min...	Max...
INSYS THERAPEUTICS INC	42	\$83,750	\$1,994	\$1,600	\$3,750

Spend for Selected Speaker



Transaction Details

Company	Payment Date	No. of Payments	Spend
INSYS THERAPEUTICS INC	4/24/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	4/22/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	4/15/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	4/8/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/28/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/22/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/21/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/15/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/14/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/8/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	1/7/2015	1	\$2,200.00
INSYS THERAPEUTICS INC	12/18/2014	1	\$2,200.00

Dr John Couch (spend vs prescriptions)

Medicine Department

Physician Name

JOHN PATRICK COUCH

Physician Specialty

Other Service Providers/ Specialist

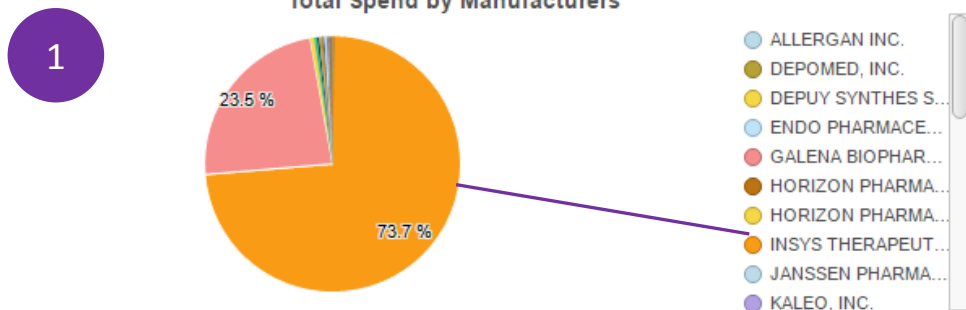
Total Drug Cost

\$6,444,867

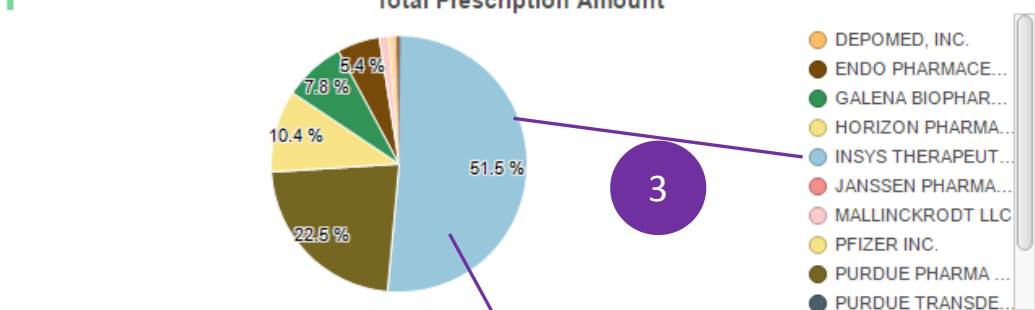
Total Spend

\$135,615

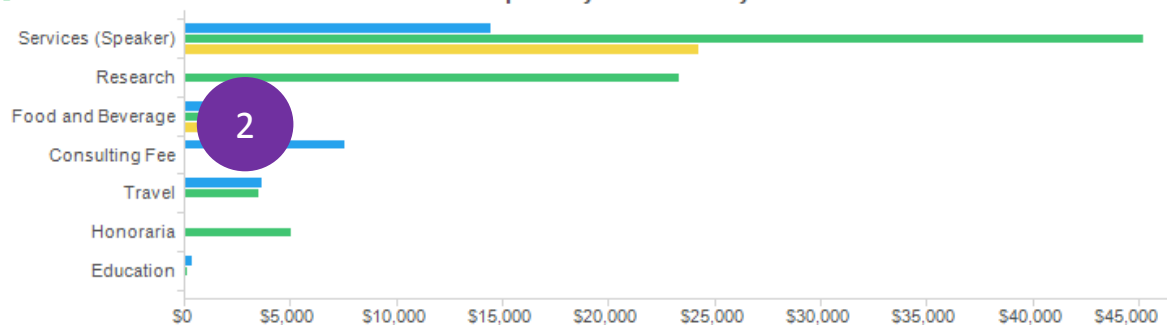
Total Spend by Manufacturers



Total Prescription Amount



Spend by Nature of Payment



Spend by Drugs

Drug Name	Spend	Prescription Amo...	Total Claims
Subsys	\$150,790	\$3,316,811	338
ABSTRAL	\$23,443	\$501,451	62
Exalgo	\$238	\$76,115	76
LYRICA	\$182	\$606,088	1,918
Nucynta	\$170	\$5,590	16
DUEXIS	\$118	\$22,640	30
BUTRANS	\$95	\$7,130	24
NUVIGIL	\$68	\$22,280	38
OXYCONTIN	\$66	\$1,448,668	1,957
Zohydro ER	\$40	\$10,993	26
C:FI FRRFX	\$28	\$61,072	225

Dr Ruan Xiulu – Speaker Programs

Home Physician Details

Select Year

- 2013
- 2014
- 2015

Speaker Programs

58

Total Speaker Program Spend

\$116,808

Avg Speaker Program Spend

\$2,812.76

Speaker Details

Physicians	Specialty	Speaker Programs	Total SP Spend	Avg SP Spend	Min SP Spend	Max SP Spend
MAHMOOD AHMAD	Allopathic & Osteopathic Physicians/Anesthesiology/...	66	\$131,088	\$1,986	\$338	\$3,750
EDWARD LUBIN	Allopathic & Osteopathic Physicians/Pain Medicine/Pa...	61	\$133,350	\$2,186	\$600	\$7,500
MITESWAR SINGH PUREWAL	Allopathic & Osteopathic Physicians/Anesthesiology	61	\$104,750	\$1,717	\$300	\$3,200
XIULU RUAN	Other Service Providers/ Specialist	58	\$163,140	\$2,813	\$390	\$4,800
PAUL HENRY WAND	Allopathic & Osteopathic Physicians/Psychiatry & Ne...	54	\$91,050	\$1,686	\$1,000	\$5,500

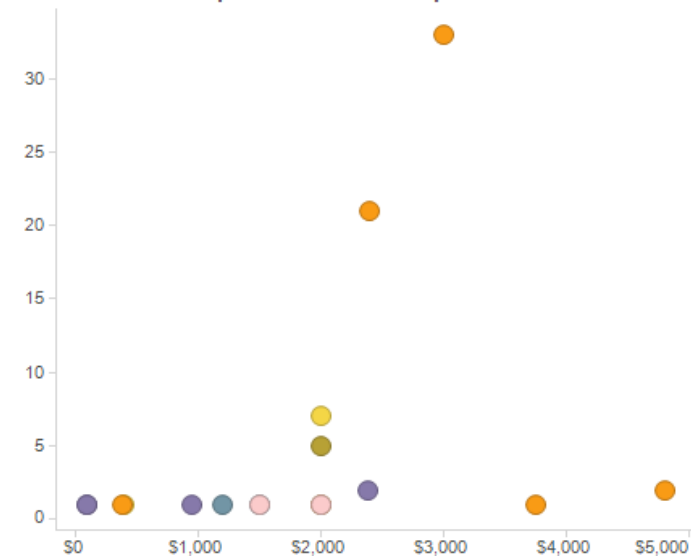
Industry Speaker Program Spend

Company	Speaker Program	Total SP Spend	Avg ...	Min...	Max...
INSYS THERAPEUTICS INC	58	\$163,140	\$2,813	\$390	\$4,800
HORIZON PHARMA USA,...	8	\$14,400	\$1,800	\$400	\$2,000
DEPOMED, INC.	5	\$10,000	\$2,000	\$2,000	\$2,000

Transaction Details

Company	Payment Date	No. of Payments	Spend
HORIZON PHARMA PLC	4/29/2015	1	\$2,000.00
INSYS THERAPEUTICS INC	4/21/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	4/17/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	4/10/2015	1	\$3,000.00
DEPOMED, INC.	2/24/2015	1	\$2,000.00
DEPOMED, INC.	2/7/2015	1	\$2,000.00
INSYS THERAPEUTICS INC	1/30/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	1/23/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	1/19/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	1/16/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	1/12/2015	1	\$3,000.00
INSYS THERAPEUTICS INC	1/9/2015	1	\$3,000.00

Spend for Selected Speaker



Dr Ruan Xiulu (spend vs prescriptions)

Medicare Details

Physician Name

XIULU RUAN

Physician Specialty

Other Service Providers/ Specialist

Total Drug Cost

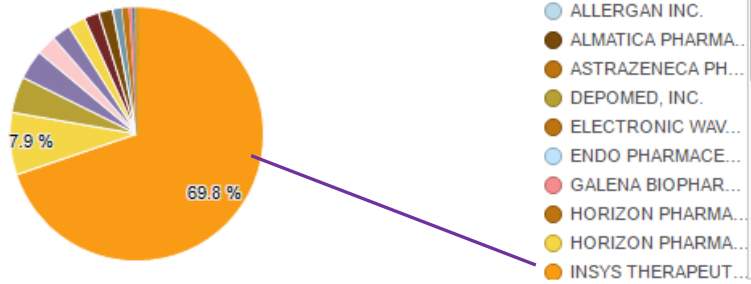
\$4,549,604

Total Spend

\$245,349

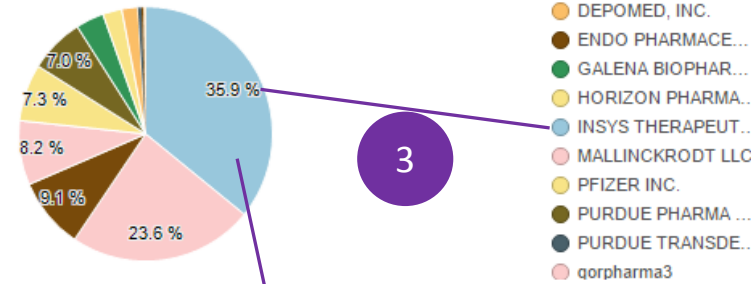
Total Spend by Manufacturers

1



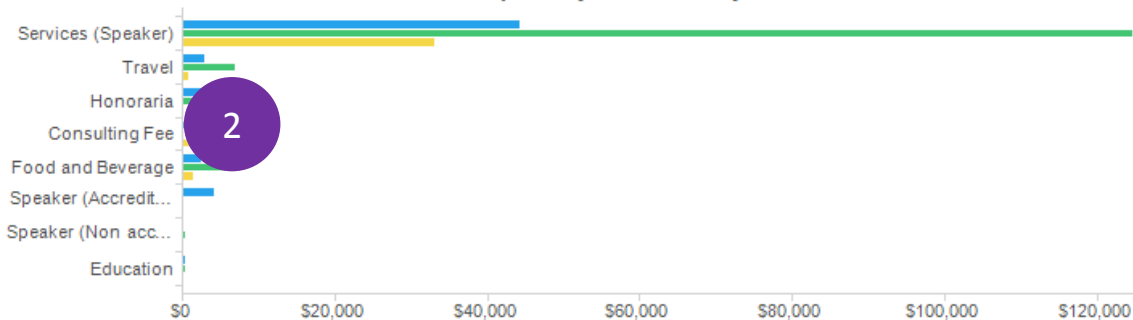
Total Prescription Amount

3



Spend by Nature of Payment

2



Spend by Drugs

● 2013
● 2014
● 2015

Drug Name	Spend	Prescription Amo...	Total Claims
Subsys	\$287,890	\$1,632,333	345
DUEXIS	\$13,426	\$88,236	104
FENTORA	\$6,884	\$957,224	191
Zohydro ER	\$6,259	\$12,644	34
BUTRANS	\$5,975	\$39,512	118
Exalgo	\$5,774	\$371,044	283
ABSTRAL	\$1,133	\$162,677	38
NUVIGIL	\$476	\$92,766	188
OXYCONTIN	\$162	\$299,012	900
OPANA ER	\$102	\$411,872	739
LYRICA	\$77	\$307,184	961

Case Study: Insys Therapeutics

The New York Times

Using Doctors With Troubled Pasts to Market a Painkiller

By KATIE THOMAS NOV. 27, 2014

[REDACTED] to promote a powerful and addictive painkiller called Subsys, according to a new federal database of payments that drug companies make to physicians.

But while Insys Therapeutics, the Arizona company that makes the product, was paying Dr. Somerville to promote it, [REDACTED] Last December, [the board ordered him](#) to stop prescribing painkillers after it found that he had authorized employees to hand out pre-signed prescriptions to patients and after it learned that three of his patients had died in 2012 of drug overdoses, most likely from drugs that he had prescribed.

Dr. Somerville, who received more money from Insys than any other doctor between August and December 2013, is just one of the company's highly paid doctors who have recently faced legal or disciplinary trouble.

Dr. Gavin Awerbuch, a Michigan neurologist who received \$56,000 from Insys, [was arrested this spring](#) after federal prosecutors said he defrauded [Medicare](#) of \$7 million and improperly prescribed Subsys to patients who did not need it. Another top Insys speaker, Dr. Jerrold Rosenberg of Rhode Island, was [reprimanded in September](#) for inappropriately prescribing painkillers, including Subsys.

[REDACTED] including three who were said to have inappropriately prescribed painkillers.

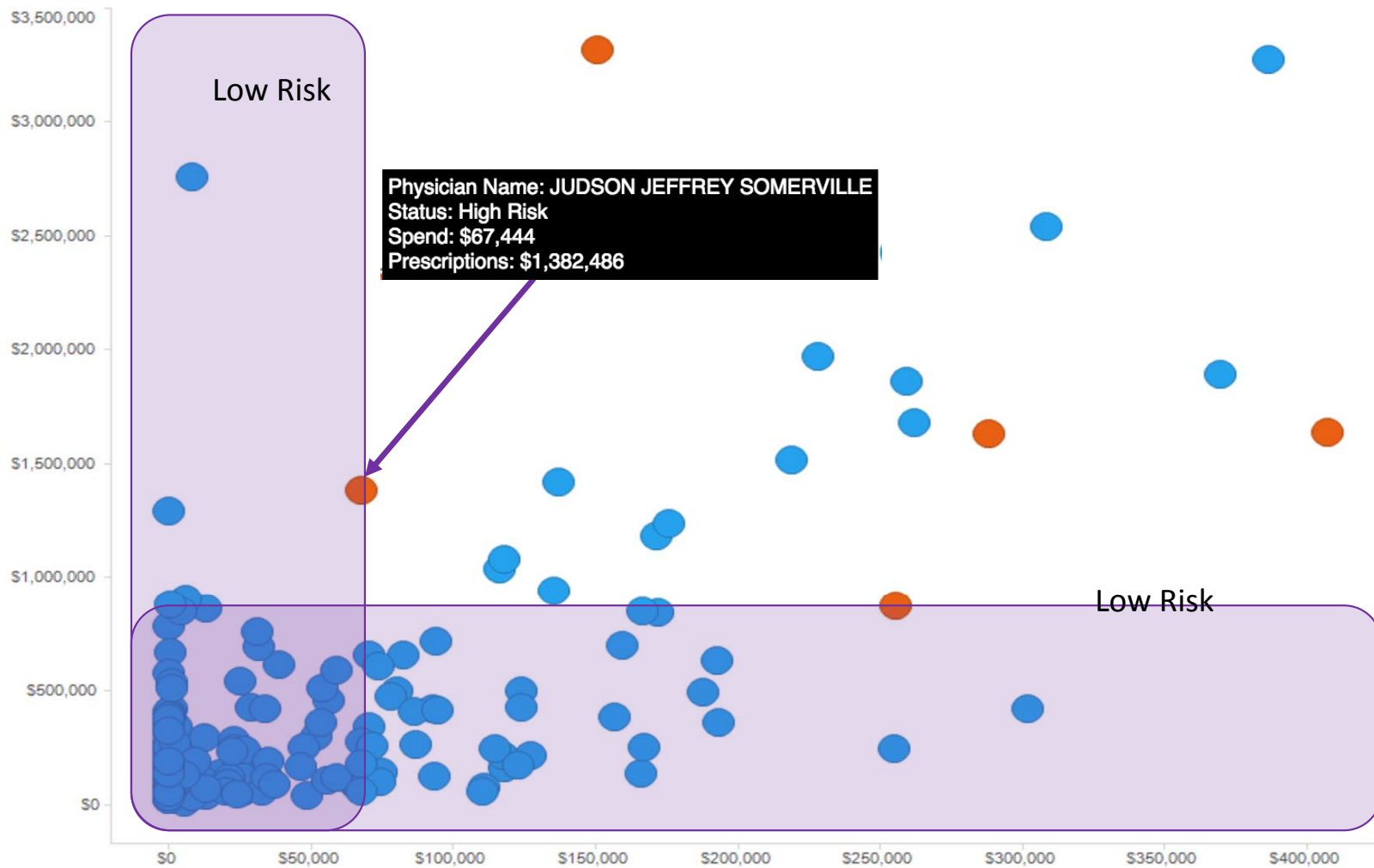
Many of the 20 highly paid doctors — most of them pain specialists — were also top prescribers of Subsys, according to prescribing information from Tricare, the health insurance program for military families, and internal Insys documents.

Insys Therapeutics

Select Company

(All) 215 values

INSYS THERAPEUTICS INC



Dr Judson Somerville – Speaker Programs

Select Year

- 2013
- 2014
- 2015

Speaker Programs

17

Total Speaker Program Spend

\$34,221

Avg Speaker Program Spend

\$3,388.24

Speaker Details

Physicians	Specialty	Speaker Programs	Total SP Spend	Avg SP Spend	Min SP Spend	Max SP Spend
BRUCE DAVID NICHOLSON	Allopathic & Osteopathic Physicians/Anesthesiology/...	17	\$49,500	\$2,912	\$2,400	\$4,750
JUDSON JEFFREY SOMERVILLE	Other Service Providers/ Specialist	17	\$57,600	\$3,388	\$2,400	\$7,200
ABEL MURILLO	Allopathic & Osteopathic Physicians/Anesthesiology/...	15	\$34,550	\$2,303	\$2,200	\$3,750
ANDREW WARREN HESSELTINE	Allopathic & Osteopathic Physicians/Anesthesiology/...	15	\$29,750	\$1,983	\$1,300	\$3,750
BENJAMIN JEFFREY DUCKLES	Allopathic & Osteopathic Physicians/Pain Medicine/Int...	15	\$28,500	\$1,900	\$1,900	\$1,900

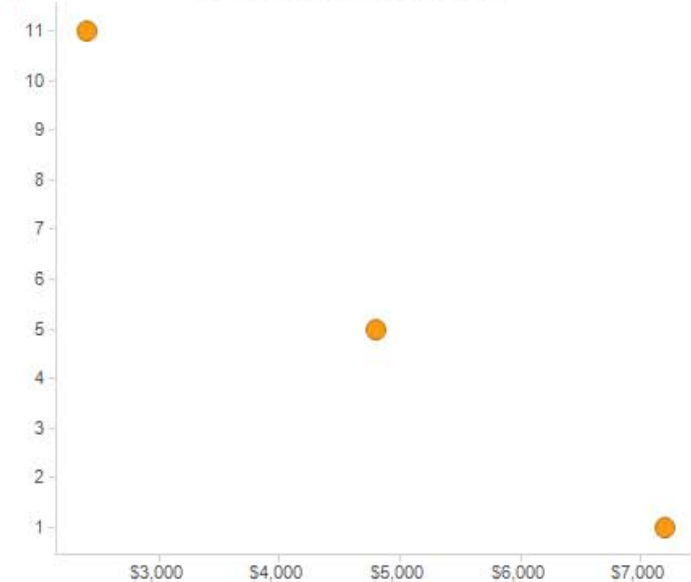
Industry Speaker Program Spend

Company	Speaker Program	Total SP Spend	Avg ...	Min...	Max...
INSYS THERAPEUTICS INC	17	\$57,600	\$3,388	\$2,400	\$7,200

Transaction Details

Company	Payment Date	No. of Payments	Spend
INSYS THERAPEUTICS INC	12/27/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	12/19/2013	1	\$4,800.00
INSYS THERAPEUTICS INC	11/25/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	11/21/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	11/14/2013	1	\$7,200.00
INSYS THERAPEUTICS INC	11/6/2013	1	\$4,800.00
INSYS THERAPEUTICS INC	11/1/2013	1	\$4,800.00
INSYS THERAPEUTICS INC	10/25/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	10/9/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	9/25/2013	1	\$2,400.00
INSYS THERAPEUTICS INC	9/18/2013	1	\$4,800.00
INSYS THERAPEUTICS INC	9/13/2013	1	\$2,400.00

Spend for Selected Speaker



Dr Judson Somerville (spend vs prescriptions)

Medicine Details

Physician Name

JUDSON JEFFREY SOMERVILLE

Physician Specialty

Other Service Providers/ Specialist

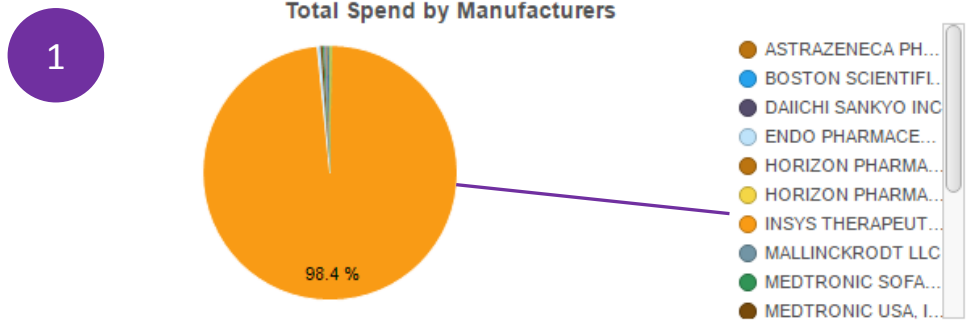
Total Drug Cost

\$1,508,440

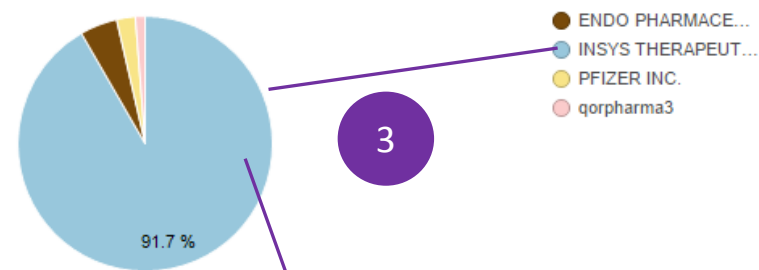
Total Spend

\$68,562

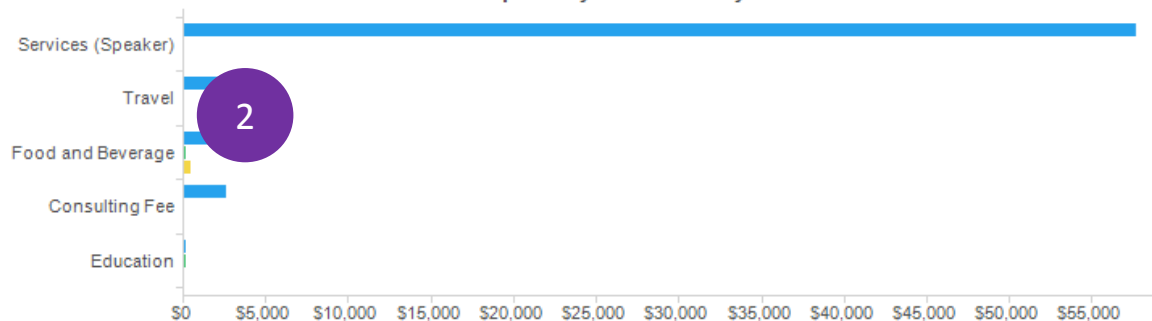
Total Spend by Manufacturers



Total Prescription Amount



Spend by Nature of Payment



Spend by Drugs

Drug Name	Spend	Prescription Amo...	Total Claims
Subsys	\$67,444	\$1,382,486	71
OPANA ER	\$220	\$71,501	67
NUVIGIL	\$34	\$18,744	39
CELEBREX	\$18	\$1,524	11
LYRICA	\$18	\$34,185	121

Case Study: Insys Therapeutics

- **Company Announced Subpoenas**
 - December 2013 from OIG requesting documents relating to commercialization of Subsys
 - September 2014 U.S. Attorney District of MA requesting documents relating to sales and marketing practices for Subsys
 - Illinois Attorney General sues Insys – August 2016

Learnings from the OIG

Office of Inspector General Update

16th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
October 21, 2015

Mary E. Riordan, Senior Counsel
Office of Counsel to the Inspector General

Lessons/Suggestions

- Kickback concerns continue
 - Think about kickback risks associated with financial relationships
 - Think “Open Payments”



Recommendations

- **Publicly available data can and will be used against you**
 - With three years of spend data available, it is only a matter of time
- **Kickback Allegations**
 - On *perception* of correlation between spend and prescriptions
 - Prosecution focus is on Consulting and Speaker fees
- **Know YOUR data!**

Thank You