

**Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd.,
Cephalon, Inc., and Actavis Generic Defendants'**

Direct Examination of Sean Nicholson, Ph.D.

June 14, 2022

Sean Nicholson, Ph.D

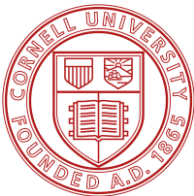


- **Education:**

- **University of Wisconsin-Madison** Ph.D. in economics, 1997
- **Dartmouth College**, A.B. in economics, *magna cum laude*, 1986;

- **Professional Experience:**

- **Cornell University:** Professor, Department of Economics and School of Public Policy (2004-present); Director, Sloan Program in Health Administration (2015-present); Weiss Presidential Fellow (2016)
- **University of Pennsylvania:** Assistant Professor, Healthcare Systems, The Wharton School (1997-2004); Helen Kardon Moss Anvil Award (2004)



Sean Nicholson, Ph.D



JAMA
The Journal of the American Medical Association



SAMHSA
Substance Abuse and Mental Health
Services Administration

- **Publications:**

- *NEJM, JAMA, Health Affairs, Journal of Health Economics, The Oxford Handbook of the Economics of the Biopharmaceutical Industry* (co-editor, 2012)

- **Grants:**

- Substance Abuse and Mental Health Services Administration (SAMHSA), Addressing Buffalo's Opioid Epidemic with Medication-Assisted Treatment (2018-2021)

- **Research Expertise:**

- Causal analysis; Pharmaceutical Industry, Health Economics, and Health Policy

Summary of Opinions

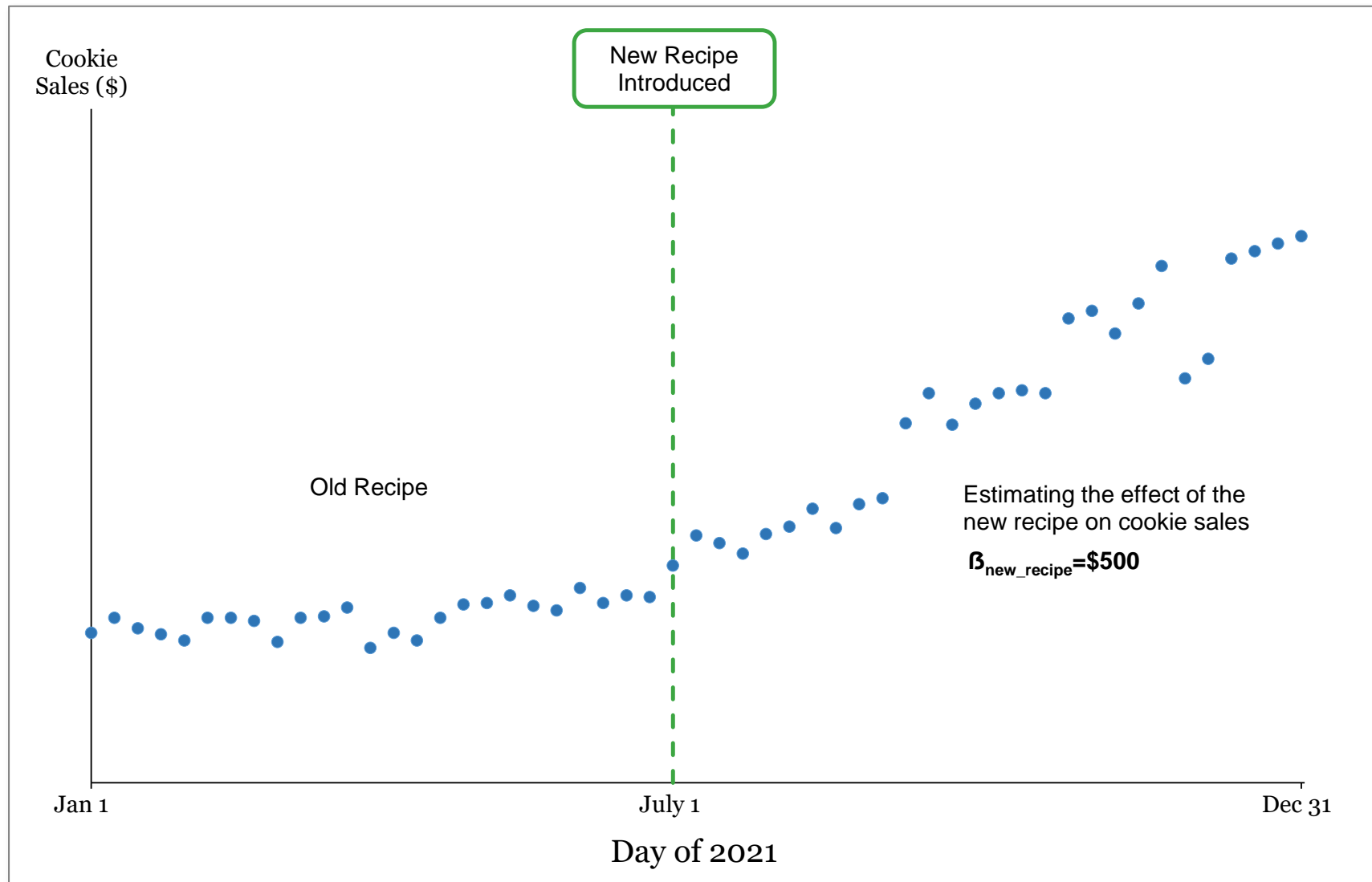
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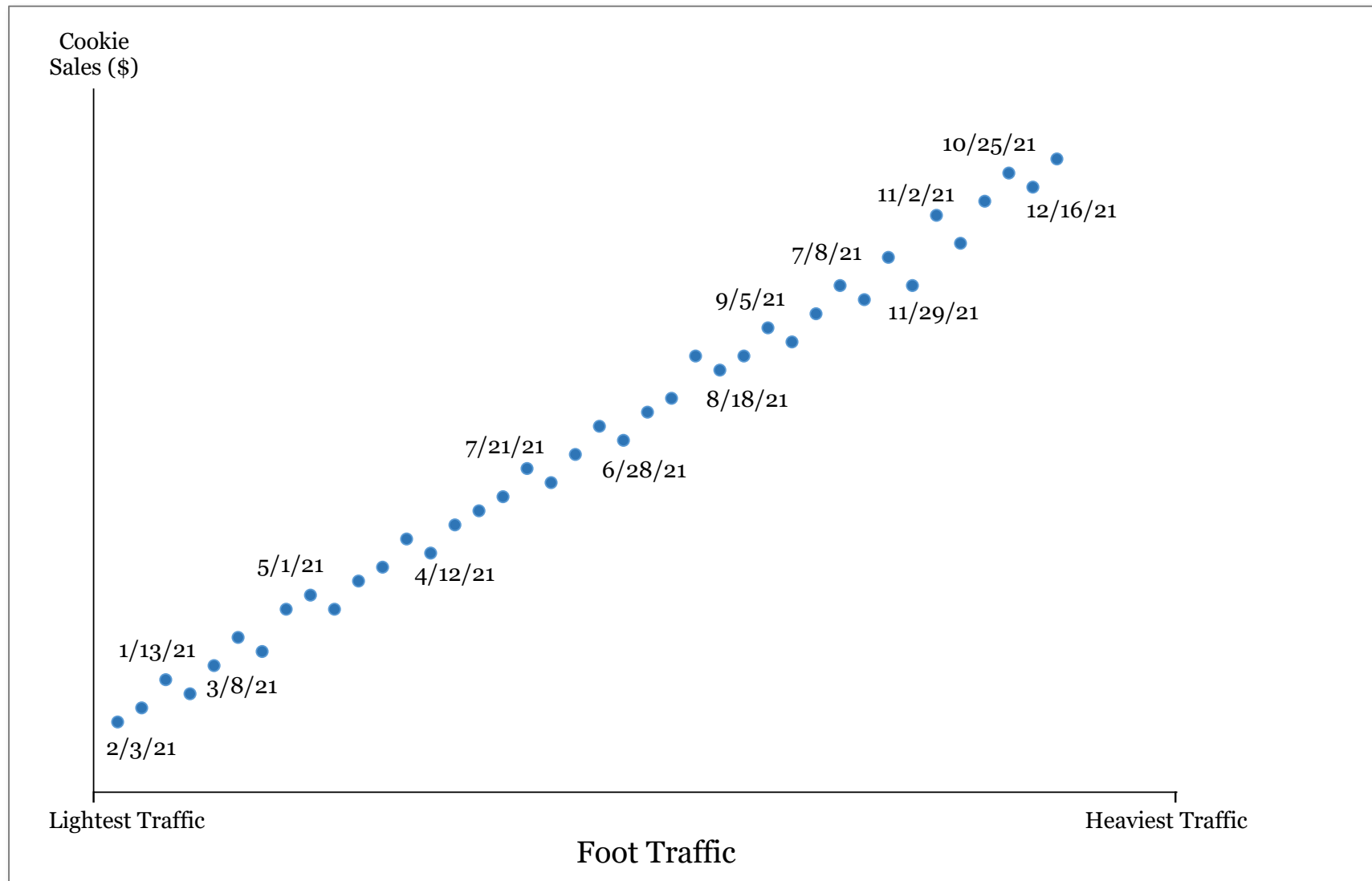
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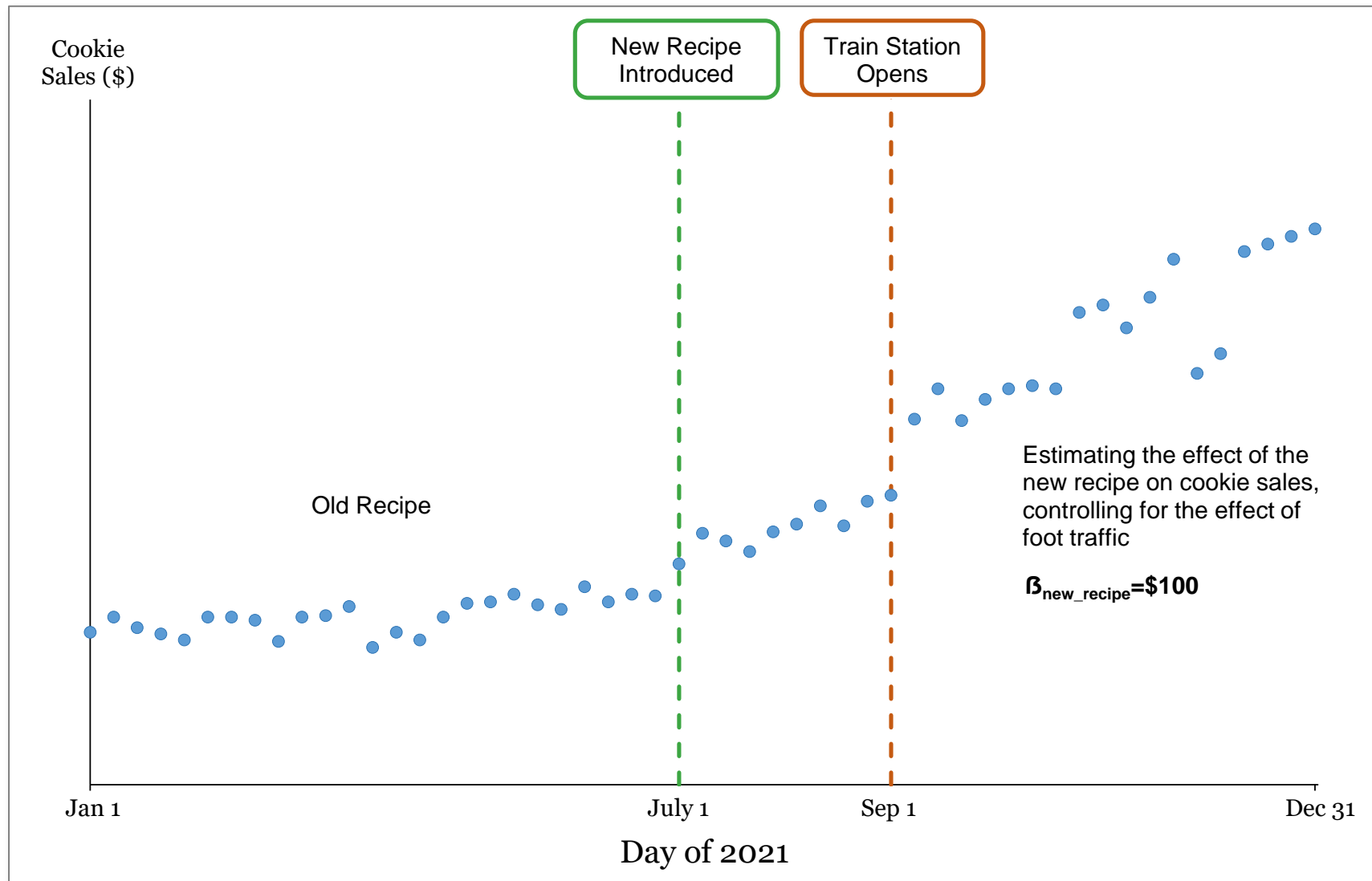
Importance of Control Variables in Causation Analysis



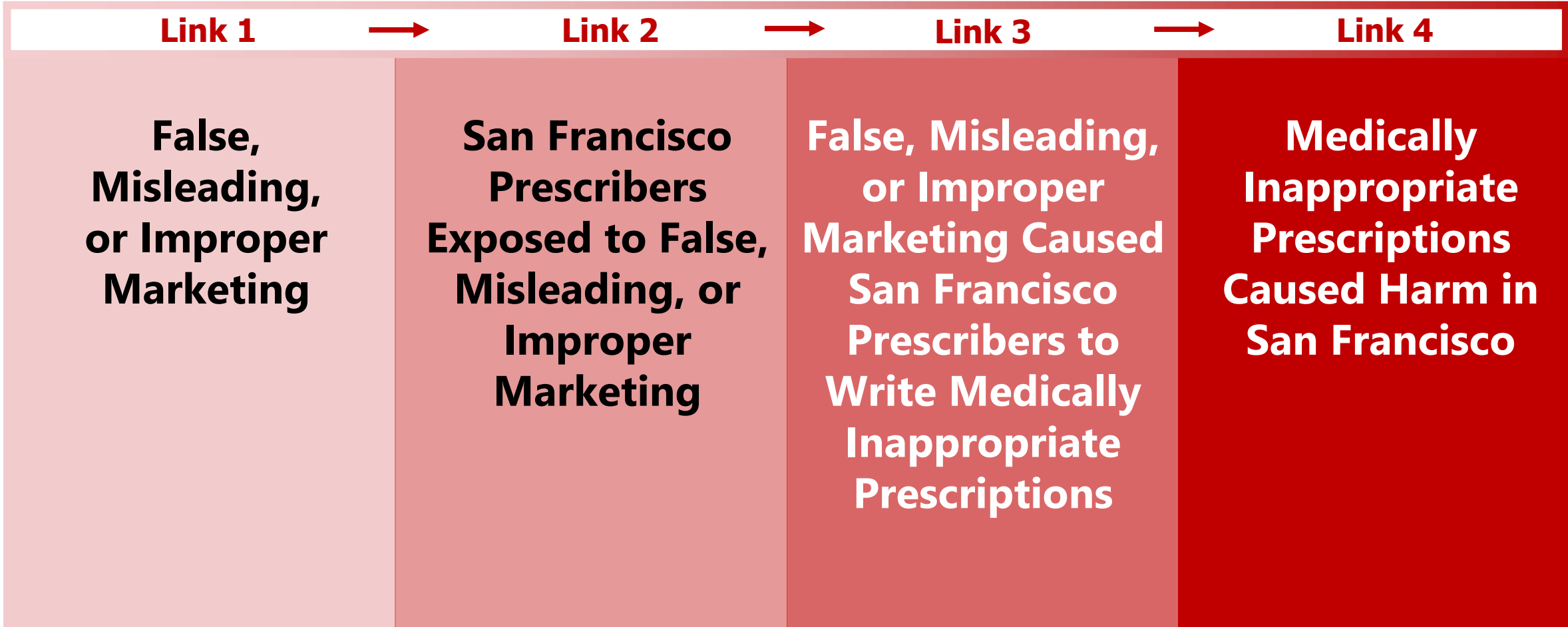
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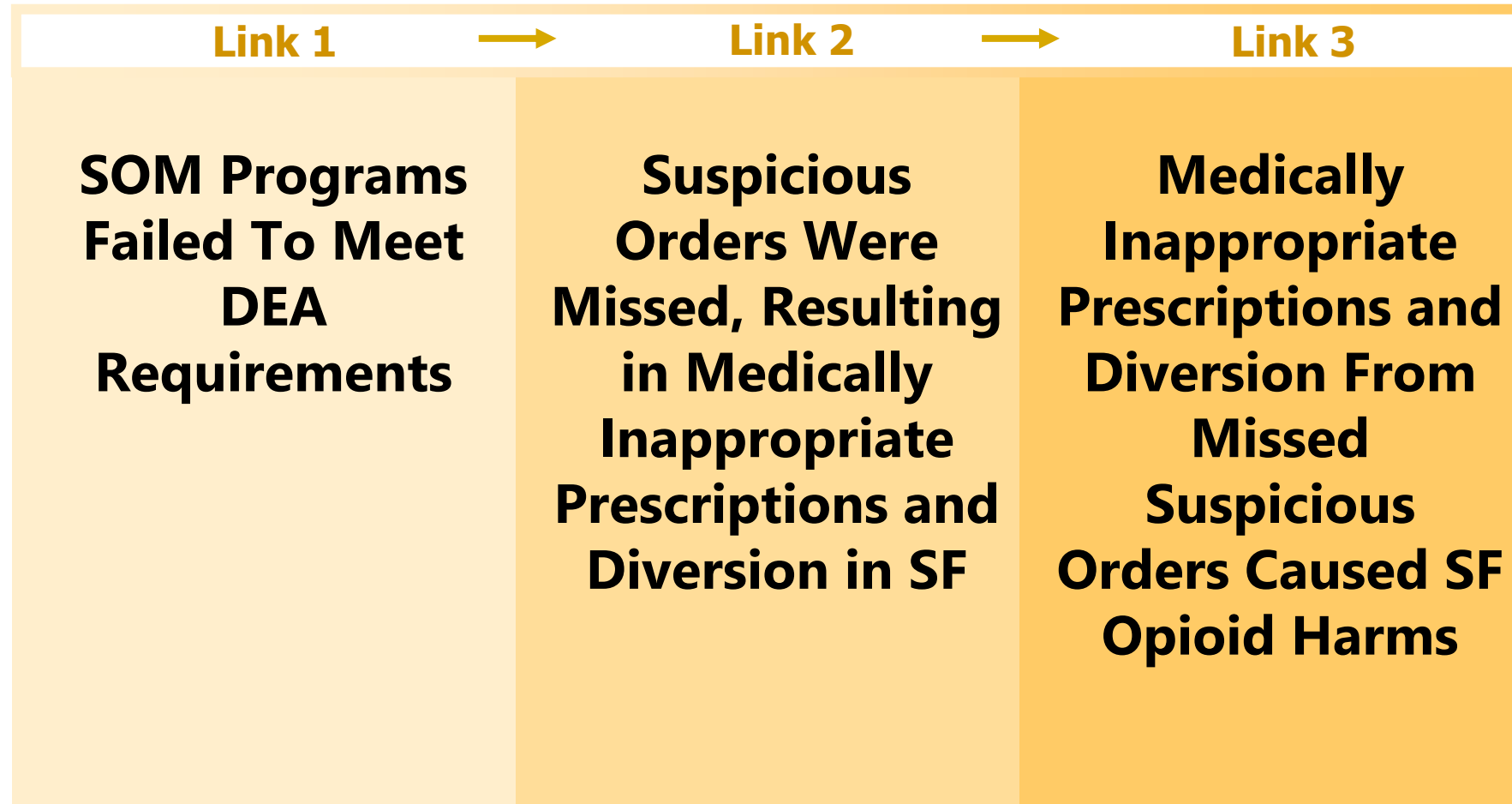
Required Marketing Causation Links



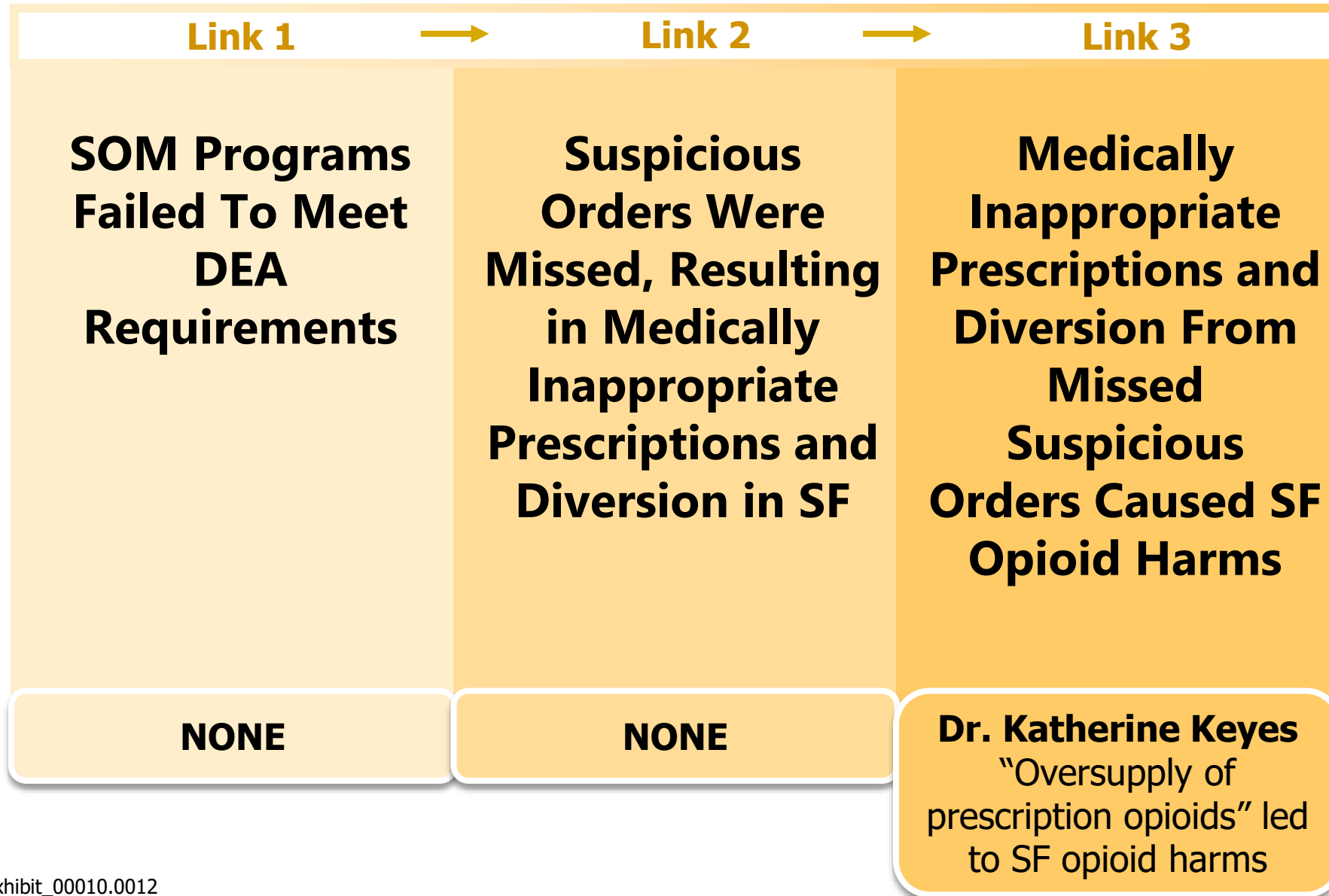
Required Marketing Causation Links



Suspicious Order Monitoring Links



Suspicious Order Monitoring Links



Opinion # 1: Miniscule Market Share

Actiq and Fentora accounted for a miniscule market volume and market share of opioid prescriptions in San Francisco from 2001 through 2018

The People's experts have failed to undertake a proper causation analysis with respect to marketing and SOM-related claims

The People's experts failed to sufficiently account for alternative factors and the conduct of actors other than Cephalon, Teva USA, or the Actavis Generic Defendants

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Opinion #1: Actiq and Fentora Had Miniscule Market Volume in San Francisco Between 2001-2018

**Total Prescriptions:
6,117**

**2001-2018:
340
Prescriptions/Year**

	Year	Actiq® <small>(oral transmucosal fentanyl citrate)</small>	FENTORA <small>fentanyl buccal tablet</small>
Cephalon	2001	297	-
	2002	491	-
	2003	552	-
	2004	784	-
	2005	977	-
	2006	859	51
	2007	153	317
	2008	59	266
	2009	18	321
	2010	3	242
	2011	-	286
Teva USA	2012	13	131
	2013	14	74
	2014	-	72
	2015	-	54
	2016	-	46
	2017	-	34
	2018	-	2

**San Francisco
Population:
> 800,000**

Opinion #1: Actiq and Fentora Had Miniscule Market Share in San Francisco Between 1997-2018

Overall Market Share:
0.056%

	Year	Actiq® <small>(oral transmucosal fentanyl citrate)</small>	FENTORA <small>fentanyl buccal tablet</small>	Total (All) Opioid Prescriptions
	1997	-		419,493
	1998	-		408,587
	1999	-		447,056
	2000	-		462,829
Cephalon	2001	297		476,627
	2002	491		480,996
	2003	552		492,623
	2004	784		498,108
	2005	977		519,138
	2006	909		520,833
	2007	471		556,999
	2008	324		574,118
	2009	340		591,170
	2010	246		609,735
	2011	286		612,319
Teva USA	2012	143		617,155
	2013	88		587,432
	2014	72		542,887
	2015	54		496,331
	2016	46		470,230
	2017	34		420,026
	2018	2		134,498
	TOTAL	6,117		10,939,190

Opinion #1: Actiq and Fentora Had Miniscule Market Share in San Francisco Between 2001-2018

**Market Share
2001-2011
(Cephalon):
0.10%**

	Year	Actiq® <small>(oral transmucosal fentanyl citrate)</small>	FENTORA <small>fentanyl buccal tablet</small>	Total (All) Opioid Prescriptions
	1997	-	-	419,493
	1998	-	-	408,587
	1999	-	-	447,056
	2000	-	-	462,829
Cephalon	2001	297	-	476,627
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	2017	34	-	420,026
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**Market Share
2012-2018
(Teva USA):
0.01%**

Opinion #1: Actiq and Fentora Had Miniscule Market Share in San Francisco Between 2001-2018

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Unique Prescribers of Actiq and Fentora Dispensed in San Francisco 2001–2018

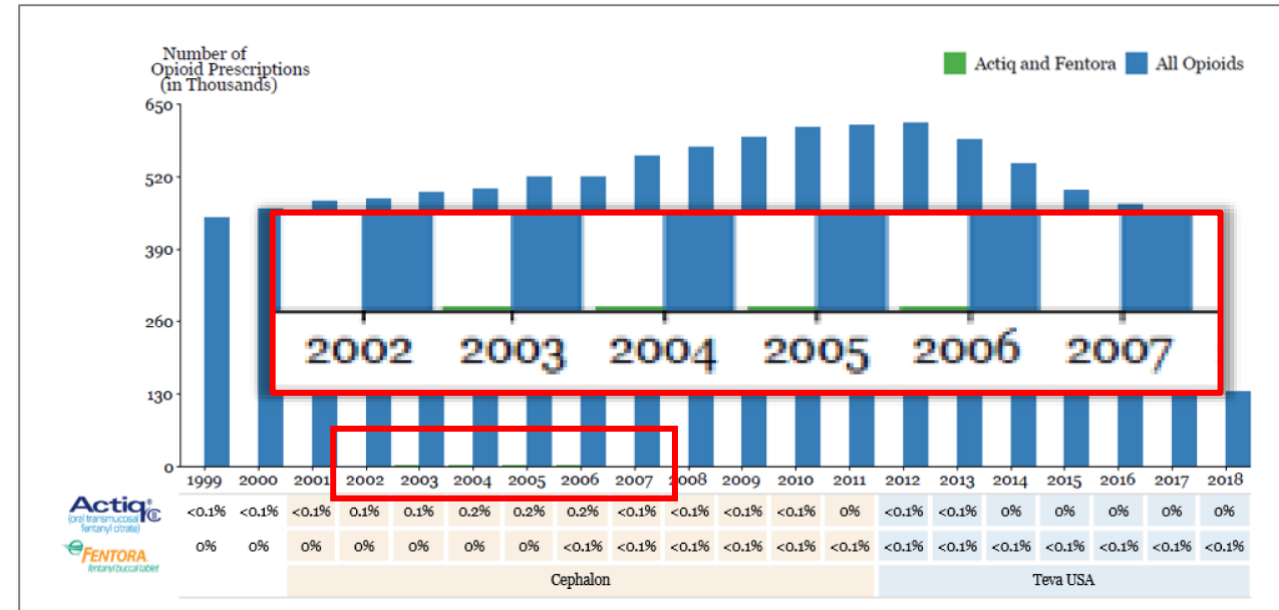
1.26
Prescriptions
Per Prescriber
Per Year

	Year	Actiq® <small>(oral transmucosal fentanyl citrate)</small>	FENTORA® <small>fentanyl buccal tablet</small>	Prescribers
Cephalon	2001	297	-	28
	2002	491	-	47
	2003	552	-	42
	2004	784	-	55
	2005	977	-	85
	2006	859	51	80
	2007	153	317	63
	2008	59	266	38
	2009	18	321	27
	2010	3	242	19
	2011	-	286	24
Teva USA	2012	13	131	13
	2013	14	74	12
	2014	-	72	8
	2015	-	54	7
	2016	-	46	5
	2017	-	34	2
	2018	-	2	1
	Total 2001-2018	4,219	1,898	Total Unique: 270

IQVIA Data, DEF-MDL-00028

Dr. Perri's "Spillover" Theory Is Unmeasured and Unsubstantiated

- **No** scientific support, empirical analysis, or quantification to determine if "spillover" exists in the SF market
- **No** scientific support, empirical analysis, or quantification to determine impact of spillover caused by miniscule market share of Actiq and Fentora on competitor medications
- **No** scientific support, empirical analysis, or quantification to determine impact of spillover on generic medications
- **No** scientific support, empirical analysis, or quantification to determine impact of spillover on all opioid medications



Nicholson Declaration, Figure 6

Opinion # 2: No Valid Causation Analysis

Actiq and Fentora accounted for a miniscule market volume and market share of opioid prescriptions in San Francisco from 2001 through 2018

The People's experts have failed to undertake a proper causation analysis with respect to marketing and SOM-related claims

The People's experts failed to sufficiently account for alternative factors and the conduct of actors other than Cephalon, Teva USA, or the Actavis Generic Defendants

The People's experts have not causally linked any alleged improper conduct to opioid-related harm specifically in San Francisco

Required Marketing Causation Links



Opinion # 3: Failure To Account for Alternative and Independent Factors

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Alternative and Independent Factors

- **“Events occurring before Cephalon, Teva USA, and the Actavis Generic Defendants Entered the Opioid Market”**
 - Nicholson Declaration ¶¶ 80-83
- **FDA and DEA**
 - Nicholson Declaration ¶¶ 84-90
- **State of California**
 - Nicholson Declaration ¶¶ 91-95
- **“Other actors in the prescription opioid supply chain”**
 - Nicholson Declaration ¶¶ 96-100

Alternative and Independent Factors: Purdue's Branded OxyContin

	Year	Actiq [®] <small>(oral transmucosal fentanyl citrate)</small> FENTORA [®] <small>fentanyl buccal tablet</small>	OxyContin Rx (Purdue)	Total Brand Rx	%OxyContin Rx (Purdue)
Cephalon	2001	297	11,997	42,598	28 %
	2002	491	13,532	42,452	32 %
	2003	552	16,949	48,791	35 %
	2004	784	16,276	46,238	35 %
	2005	977	15,746	42,741	37 %
	2006	909	6,446	30,268	21 %
	2007	471	6,424	26,019	25 %
	2008	324	21,261	38,442	55 %
	2009	340	24,940	41,759	60 %
	2010	246	24,173	40,718	59 %
	2011	286	19,978	36,046	55 %
Teva USA	2012	143	17,027	26,394	65 %
	2013	88	15,362	27,359	56 %
	2014	72	13,698	30,480	45 %
	2015	54	13,062	24,273	54 %
	2016	46	10,245	19,647	52 %
	2017	34	8,020	13,799	58 %
	2018	2	2,282	3,107	73 %
TOTAL		6,117	257,417	581,132	44 %

Purdue
OxyContin Rx
Total:
42x greater
than Actiq and
Fentora

Opinion # 4: No Causal Link Established Between Alleged Improper Conduct and Opioid-Related Harm in SF

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