IN THE CIRCUIT COURT OF KNOX COUNTY, TENNESSEE
SIXTH JUDICIAL DISTRICT AT KNOXVILLE

STATE OF TENNESSEE, *ex rel.* HERBERT H. SLATERY III, ATTORNEY GENERAL and REPORTER, Plaintiff, v. ENDO HEALTH SOLUTIONS INC., a foreign corporation, and ENDO PHARMACEUTICALS INC., a foreign corporation, Defendants.	)	JURY DEMAND Case No. 1-174-19

COMPLAINT

[SUBJECT TO MOTION TO TEMPORARILY SEAL COMPLAINT]

TABLE OF CONTENTS

I. GENERAL FACTUAL ALLEGATIONS 3

PARTIES *6*

STATE COURT JURISDICTION *7*

SUBJECT MATTER JURISDICTION *7*

PERSONAL JURISDICTION *7*

VENUE *8*

PRE-SUIT NOTICE *8*

II. SPECIFIC FACTUAL ALLEGATIONS *9*

Endo's Opioid Products *9*

A. DECEPTIVE SAFETY CLAIMS AND MATERIAL OMISSIONS *50*

Safety Claims: Abuse Deterrence Claims 51

Safety Claims: Pseudoaddiction 75

Safety Claims: Misrepresentations as to Euphoria or "Peaks and Valleys" 79

Safety Claims: Understating the Risk of Addiction 81

Safety Claims: Misrepresenting the Efficacy of Tools to Mitigate Addiction 85

Failing to Disclose Increased Risk of Addiction at Higher Doses 90

Failing to Disclose Lack of Evidence for Long-Term Use of Opioids 95

Safety Claims: General Safety Claims 98

B. DECEPTIVE COMPARATIVE CLAIMS *103*

C. DECEPTIVE BENEFIT CLAIMS *114*

D. DECEPTIVE CLAIMS ABOUT OPIOID USE IN THE ELDERLY *120*

E. OMISSIONS OF MATERIAL CONNECTIONS *126*

F. ENDO IS SUBSTANTIALLY RESPONSIBLE FOR THE OPIOID EPIDEMIC IN TENNESSEE *130*

III. VIOLATIONS OF THE LAW 169

COUNT I: TENNESSEE CONSUMER PROTECTION ACT *169*

COUNT II: COMMON LAW NUISANCE *174*

IV. PRAYER FOR RELIEF 177

1. Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. (collectively Endo) unlawfully marketed their opioid products in Tennessee including to notorious pill mills and health care providers that Endo knew or should have known showed red flags for opioid abuse or diversion. The State of Tennessee brings this civil enforcement action to hold Endo accountable for its violations of the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101 to -131 (TCPA), to protect the public, to preserve the integrity of the marketplace, and to abate and remedy the public nuisance created by Endo's marketplace interference and endangerment of public health in Tennessee.

2. The State's enforcement action seeks injunctive relief, civil penalties for Endo's violations of law, disgorgement of its unjust gains, abatement of the public nuisance Endo substantially helped to create, and recoupment of the State's costs.

I. GENERAL FACTUAL ALLEGATIONS

3. Opioids are natural, synthetic, or semi-synthetic derivatives of opium. Historically, opioids were prescribed in limited circumstances because of long-standing and well-founded fears about their addictive potential and safety. Opioid manufacturers like Endo sought to reverse this well-established practice through marketing that was highly aggressive and deceptive.

4. Purdue Pharma (Purdue) laid the groundwork for the reversal of this practice with its launch of OxyContin (extended release oxycodone), which generated windfall profits, significantly expanded the once-narrow market for extended release opioids, and provided the marketing blueprint for later competitors. Endo wanted its own OxyContin and sought to outdo Purdue in both drug potency and marketing. In order to break into the market with its flagship opioid drug, Opana ER (extended release oxymorphone hydrochloride), which was twice as potent as OxyContin, Endo intensified the pieces of the OxyContin marketing campaign that made

Purdue's marketing so effective and devastating, and engaged in activity that even Purdue generally avoided. Like Purdue, Endo repeatedly picked profits over people, but did so with Opana ER starting in 2006 after the adverse impact of Purdue's conduct became well-known through congressional hearings and other high-profile investigations.

5. Endo ramped up its marketing to pill mills in Tennessee to make providers switch from Purdue's OxyContin to Opana ER following a 2010 change to OxyContin's formulation that purportedly made OxyContin more resistant to certain forms of abuse. Based on its own marketing surveillance, Endo knew almost in real time that the growth of Opana ER sales was due to its deceptive marketing and consumers' dissatisfaction with reformulated OxyContin. The company also quickly knew that Opana ER was "showing the most gain during OxyContin['s] loss" and that "abuse behavior [was] driving [the] decline in OxyContin use." Endo capitalized on OxyContin's reduced popularity among opioid abusers and diverters following its reformulation and worked to ensure that Purdue's loss was Endo's gain.

6. Endo was desperate to maintain its revenue stream for Opana ER and deceptively promoted a reformulated Opana ER as abuse deterrent to ward off generic competitors despite knowing that:

- the FDA had explicitly rejected such claims for Opana ER's product label;
- the FDA unequivocally told Endo its claims were misleading and could jeopardize public health;
- Endo's own studies predicted intravenous abuse of the reformulated Opana ER;
- intravenous use of the reformulated Opana ER "could not be prevented" because of oxymorphone's water solubility;
- the reformulated Opana ER could be easily manipulated to release the whole dose (i.e. dose dump) through cutting;
- Endo had withdrawn Opana ER's predecessor, Numorphan, from the market following reports of intravenous abuse in 1982;

- Endo's own data showed that reformulated Opana ER was even more susceptible to abuse by injection and cutting than its old formulation;
- Endo's reformulated Opana ER had *three times* the prevalence rate of abuse *in Tennessee* compared to the old formulation;
- intravenous abuse of Opana ER through cutting was occurring in significant numbers, including through a cluster of individuals in Kingsport, Tennessee and elsewhere who contracted a Thrombotic Thrombocytopenic Purpura (TTP)-like blood disorder, sepsis, and/or Hepatitis C following intravenous use of Opana ER; and
- numerous Tennesseans overdosed or died following intravenous abuse of Opana ER.

7. Endo's misleading claims about the purportedly lower abuse potential of Opana ER featured prominently in its marketing campaigns, but Endo also made many other material misrepresentations and omissions. Endo violated the TCPA by making a series of unlawful safety, comparative, and benefit claims about its opioid products, failing to disclose its material connection to third-party pain advocacy groups it substantially funded, and unfairly targeting vulnerable populations like the elderly. Specifically, Endo advanced deceptive claims that its opioid products were safer than they actually were, its competitors' products were more dangerous or less effective than they actually were, its opioid products had certain qualities or benefits for which it lacked legally-required substantiation, and its opioid products were safer for elderly patients than they actually were.

8. Endo targeted high-volume opioid prescribers in Tennessee, pushing them to prescribe even more of its opioid products through deceptive claims. Endo's sales representatives called on Tennessee prescribers who had little or no background in pain management, including those engaged in specialties like podiatry, gynecology, sleep medicine, medical genetics, and adolescent medicine (which even Purdue was hesitant to call upon). Moreover, Endo ignored evidence of opioid abuse or diversion at the locations of many of the providers its sales representatives called upon.

9. Endo's actions and omissions concerning its highly addictive, powerful narcotics have created and fueled a public nuisance in Tennessee by significantly interfering with the commercial marketplace and endangering public health in the state.

10. The culmination of Endo's marketing activities *resulted in Tennessee having the highest prescription rates of Opana ER in the country*, a wave of addiction, overdoses, and overdose deaths, and the spread of a rare blood disorder and Hepatitis C across Tennessee. Endo likely inflicted more harm on Tennessee than any other state.

PARTIES

11. Plaintiff, the State of Tennessee *ex rel*. Herbert H. Slatery III, Attorney General and Reporter, is charged with enforcing the TCPA. Under Tenn. Code Ann. § 47-18-108, actions for violations of the TCPA may be brought only by the Attorney General in courts of competent jurisdiction to restrain violations, to secure equitable and other relief, and to otherwise enforce the provisions of the TCPA. The Attorney General has all common law powers except as restricted by statute, *State v. Heath*, 806 S.W.2d 535, 537 (Tenn. Ct. App. 1990), and is expressly authorized to utilize and refer to the common law in the exercise of his duties under Tenn. Code Ann. § 8-6-109(a).

12. Defendants Endo Health Solutions Inc. and its wholly-owned subsidiary, Endo Pharmaceuticals Inc., are both Delaware corporations with a principal place of business in Malvern, Pennsylvania.

13. Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. acted in concert with one another and acted as agents and/or principals of one another in relation to the conduct described in this Complaint.[1]

[1] *See, e.g.*, ENDO-OR-CID-00014954; ENDO-OR-CID-00029899.

STATE COURT JURISDICTION

14. The causes of action asserted and the remedies sought in this Complaint are based exclusively on Tennessee statutory, common, or decisional law.

15. The State's Complaint does not confer diversity jurisdiction upon federal courts pursuant to 28 U.S.C. § 1332, as the State is not a citizen of any state and this action is not subject to the jurisdictional provisions of the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d). Federal question subject matter jurisdiction under 28 U.S.C. § 1331 is not invoked by the Complaint. Nowhere does the State plead, expressly or implicitly, any cause of action or request any remedy that arises under federal law. The issues presented in the allegations of this Complaint do not implicate any substantial federal issues and do not turn on the necessary interpretation of federal law. There is no federal issue important to the federal system as a whole, as set forth in *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

16. In this Complaint, the State references federal statutes, regulations, or actions, but does so only to establish Endo's knowledge or to explain how Endo's conduct has *not* been approved by federal regulatory agencies.

SUBJECT MATTER JURISDICTION

17. As a court of general jurisdiction, the circuit court is authorized to hear this matter based on the TCPA and nuisance claims, the amount at issue, and the relief sought pursuant to Tenn. Code Ann. §§ 16-10-101 and -110.

PERSONAL JURISDICTION

18. As set forth below, this Court has personal jurisdiction over Endo based on its contacts in Tennessee. Endo has promoted, marketed, advertised, and sold its opioid products in Tennessee, including Percocet and Opana IR (immediate release), and previously Opana ER

(extended release). Endo has transacted business in Tennessee[2] including through sales representatives who made sales calls to health care providers in Tennessee. Endo has mailed, delivered, or otherwise made marketing or promotional materials for its opioid products available to health care providers and consumers in Tennessee. Endo Pharmaceuticals Inc. previously operated a facility in Memphis, Tennessee that distributed the opioids at issue in this lawsuit, including Opana ER.[3]

VENUE

19. Venue is proper in Knox County pursuant to the TCPA's specific State enforcement venue provision, Tenn. Code Ann. § 47-18-108(a)(3), because it is a county where alleged violations took place and is also a county in which Endo has conducted or transacted business.

20. Endo marketed its opioids in Knox County through numerous in-person visits by its sales representatives to health care providers in Knoxville and throughout Knox County. Indeed, some of Endo's best performing sales force territories in the whole country were in or around Knoxville, Tennessee.[4]

PRE-SUIT NOTICE

21. Consistent with Tenn. Code Ann. § 47-18-108(a)(2), the State has provided Endo with 10 days' advance notice of its intention to initiate legal proceedings.

---

2 ENDO-OR-CID-00607702; ENDO-OR-CID-00178528 (Top Footprints tab).

3 ENDO-OR-CID-00044048; ENDO-OR-CID-00372822 (stating Memphis was distribution center for all products).

4 ENDO-OR-CID-00225751 (Opana_Territory Tab); ENDO-OR-CID-00535881 (Opana ER tab); ENDO-OR-CID-00079463; ENDO-OR-CID-00431499; ENDO-OR-CID-00486812 (Opana ER Territory tab, row 96).

II. SPECIFIC FACTUAL ALLEGATIONS

Endo's Opioid Products

22. Purdue's 1996 launch of OxyContin, a highly-potent, extended release oxycodone, was a watershed event that provided a blueprint to other opioid manufacturers seeking to duplicate Purdue's financial success. Never before had a pharmaceutical manufacturer used highly-aggressive marketing tactics on such a large scale for a dangerous and addictive Schedule II narcotic. Endo wanted its own version of OxyContin and sought to outdo Purdue to establish a flagship opioid drug in the marketplace.

23. By 1996, Endo had extensive experience with product launches and marketing for opioids. In 1950, Endo launched Percodan, an oxycodone and aspirin combination product. In 1959, Endo launched Numorphan, an immediate release oxymorphone product that was the precursor to Opana, and which Endo had to withdraw from the market in 1982 following reports that people were abusing Numorphan via injection.[5] In 1971, Endo launched Percocet, an immediate release oxycodone and acetaminophen combination product. Endo later obtained approval for new dose strengths of Percocet in 1997.

24. Purdue's OxyContin success allowed it to significantly expand and initially dominate the extended release opioid market. The company built its empire in four key ways: (1) making deceptive claims about OxyContin's safety, comparative benefits, and efficacy to the public and well-intentioned health care providers; (2) focusing on physicians who were generalists, nurse practitioners, and physician assistants who generally had less expertise in pain management

[5] Ellen Fields, MD, MPH, *Regulatory History of Opana ER*, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, U.S. FOOD AND DRUG ADMINISTRATION, (March 13-14, 2017), *available at* https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf (slide 5).

and were more receptive to marketing from sales consultants; (3) ramping up its sales calls to high-volume prescribers that it knew or should have known had practices where opioid abuse or diversion was occurring; and (4) getting FDA approval for an abuse deterrent reformulation of OxyContin that removed its generic competitors from the market, allowed Purdue to make a modest abuse-deterrence claim, and extended its patent protection for the drug.

Opana ER (original formulation)

25. Endo co-opted and amplified the core elements of Purdue's OxyContin launch that made it successful (and devastating): aggressive, deceptive marketing for a potentially dangerous and potent extended release opioid. Endo positioned Opana ER, a more powerful tablet version of Numorphan, to be its "flagship" drug[6]—its very own OxyContin.

26. Endo made sure that the active ingredient for Opana ER was *twice* as potent as OxyContin's active ingredient,[7] hired more sales representatives than Purdue to make even more sales calls,[8] pushed the high strength doses of Opana ER, sought to poach OxyContin's high-dose prescribers,[9] and called on Tennessee specialists with a suspect need to prescribe extended release opioids, like podiatrists, gynecologists, sleep doctors, medical geneticists, and pediatric or adolescent specialists,[10] something that even Purdue was hesitant to do.

---

6 ENDO-OR-CID-00223050.

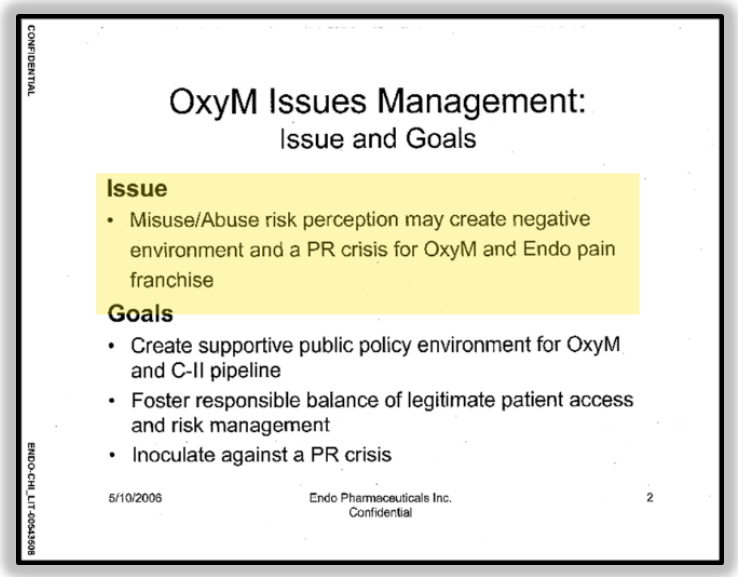
7 *Making a Difference Powerpoint*, CIBC WORLD MARKETS 14TH ANNUAL HEALTHCARE CONFERENCE, ENDO PHARMACEUTICALS INC., (Nov. 12, 2003), *available at* https://www.sec.gov/Archives/edgar/data/1100962/000095012303012517/y91613exv99w1.htm (stating "Market Need Addressed: . . . We believe that it will provide equivalent analgesia with only half the milligram dosage of OxyContin") (slide 15 of [23); ENDO-CHI_LIT-00539167; ENDO-CHI_LIT-00545554 (slides 10, 12 of 35).

8 ENDO-CHI_LIT-00541091; *See also*, ENDO-CHI_LIT-00545554 (slide 30 of 35).

9 ENDO-OR-CID-00735586 (Simulation tab).

10 ENDO-OR-MASS-CIDS_0000001; OPANA_ER_CALLS_ALL_STATEs_2017019.

27. From the outset, Endo was aware of OxyContin's tainted history concerning abuse, diversion, and public safety,[11] but adopted many of the key components of Purdue's marketing and other practices for OxyContin anyway. Before Opana immediate release (IR) and extended release (ER) were even launched in 2006,[12] Endo's consultant prepared a set of crisis management strategies for Endo. This Endo crisis management strategies report, which Endo reviewed, identified Tennessee as one of OxyContin's "crisis states,"[13] listed Tennessee among a handful of "Hot-Button" states for the U.S. Drug Enforcement Administration (DEA) Office of Diversion,[14] identified Tennessee as a key state for "issues management" related to Opana ER, anticipated that "misuse/abuse risk perception may create [a] negative environment and a PR crisis for [Opana ER] and Endo pain franchise,"[15] and prepared for news stories about high levels of abuse of Opana ER similar to OxyContin.[16]



[11] ENDO-CHI_LIT-00543498.

[12] ENDO-CHI_LIT-00545554 (slide 6 of 35); ENDO-OR-CID-00008192.

[13] ENDO-CHI_LIT-00543525.

[14] ENDO-CHI_LIT-00543578.

[15] ENDO-CHI_LIT-00543508 (highlighted emphasis added to image).

[16] ENDO-CHI_LIT-00543401; ENDO-CHI_LIT-00543523, -524; *see also*, ENDO-CHI_LIT-00543534.

28. Prior to the launch of Opana ER, initially conceived under the name "OxyM," Endo's consultant recommended that Endo:

- identify [an] area [at Endo's offices] for peaceful demonstrating and determine private/public property boundaries[;]
- [b]rief building facility staff regarding actions for non-threatening and threatening demonstrators[; and]
- [n]otify building landlord of product that may result in negative attention[,]

among other things.[17]

29. Endo's consultant recommended that the company form an 11-member Opana "Issues Management Sub-Team,"[18] which the company accepted,[19] and told Endo to expect "crisis scenarios" involving Opana ER abuse including:

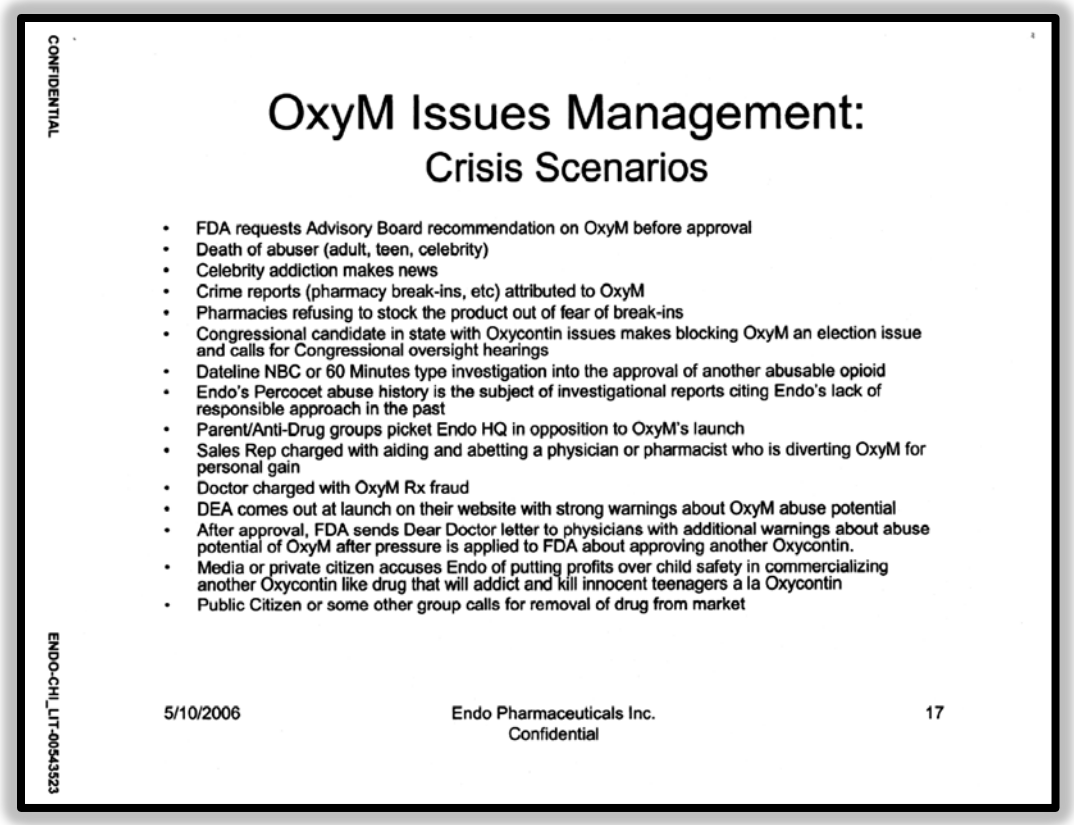
- Death of abuser (adult, teen, celebrity)[;]
- Crime reports (pharmacy break-ins, etc[.]) attributed to OxyM [Opana ER;]
- Endo's Percocet abuse history is the subject of investigational reports citing Endo's lack of responsible approach in the past[;]
- Parent/Anti-Drug groups picket Endo HQ in opposition to OxyM's launch[;]
- After approval, FDA sends Dear Doctor letter to physicians with additional warnings about abuse potential of OxyM after pressure is applied to FDA about approving another OxyContin [; and]
- Media or private citizen accuses Endo of putting profits over child safety in commercializing another OxyContin like drug that will addict and kill innocent teenagers a la Oxycontin.[20]

[17] ENDO-CHI_LIT-00543496.

[18] ENDO-CHI_LIT-00543544.

[19] ENDO-CHI_LIT-00543417.

[20] ENDO-CHI_LIT-00543523.



CONFIDENTIAL

OxyM Issues Management:
Crisis Scenarios

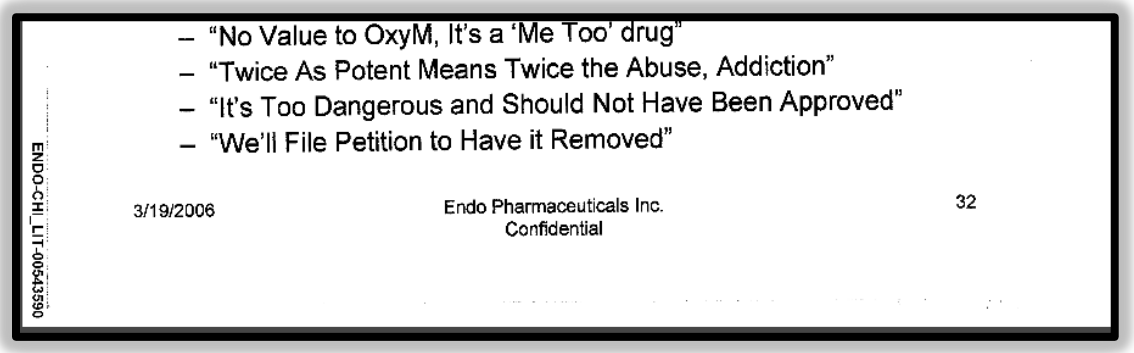
- FDA requests Advisory Board recommendation on OxyM before approval
- Death of abuser (adult, teen, celebrity)
- Celebrity addiction makes news
- Crime reports (pharmacy break-ins, etc) attributed to OxyM
- Pharmacies refusing to stock the product out of fear of break-ins
- Congressional candidate in state with Oxycontin issues makes blocking OxyM an election issue and calls for Congressional oversight hearings
- Dateline NBC or 60 Minutes type investigation into the approval of another abusable opioid
- Endo's Percocet abuse history is the subject of investigational reports citing Endo's lack of responsible approach in the past
- Parent/Anti-Drug groups picket Endo HQ in opposition to OxyM's launch
- Sales Rep charged with aiding and abetting a physician or pharmacist who is diverting OxyM for personal gain
- Doctor charged with OxyM Rx fraud
- DEA comes out at launch on their website with strong warnings about OxyM abuse potential
- After approval, FDA sends Dear Doctor letter to physicians with additional warnings about abuse potential of OxyM after pressure is applied to FDA about approving another Oxycontin.
- Media or private citizen accuses Endo of putting profits over child safety in commercializing another Oxycontin like drug that will addict and kill innocent teenagers a la Oxycontin
- Public Citizen or some other group calls for removal of drug from market

5/10/2006 Endo Pharmaceuticals Inc. Confidential 17

ENDO-CHI_LIT-00543523

30. Endo expected objections from the public, competitors, and regulators before Opana's launch in 2006 including the following:

- "No Value to OxyM, It's a 'Me Too' drug[;]"
- "Twice As Potent Means Twice the Abuse, Addiction[; and]"
- "It's Too Dangerous and Should Not Have Been Approved[.]"



- "No Value to OxyM, It's a 'Me Too' drug"
- "Twice As Potent Means Twice the Abuse, Addiction"
- "It's Too Dangerous and Should Not Have Been Approved"
- "We'll File Petition to Have it Removed"

3/19/2006 Endo Pharmaceuticals Inc. Confidential 32

ENDO-CHI_LIT-00543590

31. Endo intended to aggressively market Opana ER from the very beginning. In a draft 2007 Business Plan Review, Endo's marketing department even expressly stated its intention to "*[a]ggressively execute* 1st half 2007 activities and tactics for the OPANA brand *to drive results*[.]"[21]

32. Endo continued to aggressively and deceptively market Opana ER despite consequences Purdue was facing because of its own aggressive and deceptive marketing of OxyContin. By mid-2007, Endo knew that three Purdue executives pleaded guilty to federal criminal charges that they misled regulatory agencies, doctors, and patients about OxyContin's risk of addiction and potential to be abused. Endo knew that Purdue was fined $600 million. Endo took notes on Purdue's congressional hearings and knew that Purdue had settled with 26 states, including Tennessee, for misrepresentations about the safety and addictive potential of OxyContin.

33. As part of its marketing activities and tactics, Endo made many of the same material misrepresentations and omissions as Purdue and called on many of the same high-prescribing health care providers whose practices showed red flags for abuse and diversion.

34. In 2007, Endo's marketing consultants advised the company to position Opana ER as a safer alternative to OxyContin that "enables a better lifestyle to keep patients healthier" with "fewer strong side effects," "less euphoria," less abuse, and without OxyContin's "baggage," as documented in excerpts of an Endo presentation titled "*Better the Devil you Know* . . . Inspiring Physicians to Do the Right Thing with Opana ER."[22]

---

21 ENDO-CHI_LIT-00547007 (slide 2 of 52) (emphasis added).

22 ENDO-OR-CID-00733299 (slides 1, 14, 35 of 120).

Revised Physician's Concept

Opana ER:
Doing The Right Thing for You and Your Patients

Patients with chronic pain need real help. It's not just about *comfort* - its about keeping them engaged in a healthier lifestyle to avoid a downward spiral of mental and physical health. Schedule 2 opioids are a powerful tool in pain management, but their use raises concerns about drug seeking, product diversion, and risk to your practice and your reputation.

Opana ER is different. It's designed so you can do the right thing for your patients in pain, while shielding your practice from these risks. Unlike most ER opioids that exhibit a rapid up-front release (resulting in euphoria), and a rapid decline in effect (resulting in breakthrough pain), Opana ER's matrix provides a smoother, more consistent release for 12 hours. The result is less euphoria, and more consistent, long lasting pain control.

So it's the right drug to help real chronic pain sufferers get on with healthier lives, and an unattractive target for drug seekers. It lets you do the best thing for your patients, and the right thing for your practice.

Opana ER. A more responsible opioid.

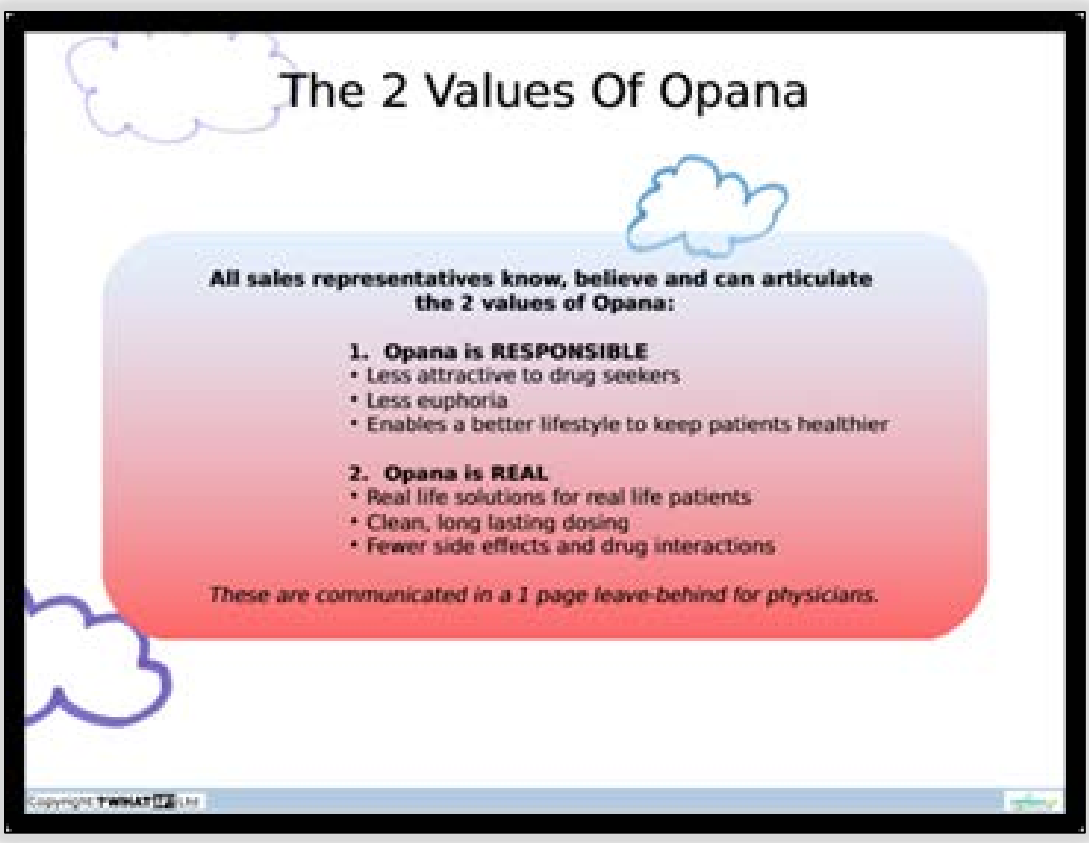
" 'Responsible' really speaks to me,"

" Lack of euphoria is powerful."

" We all have drugs we run to… <u>This</u> convinces me to use it versus my current choices"

" I wish you could tell me it was harder to snort, bite, shoot…"

" Healthy lifestyle is very positive…it takes away the stigma."

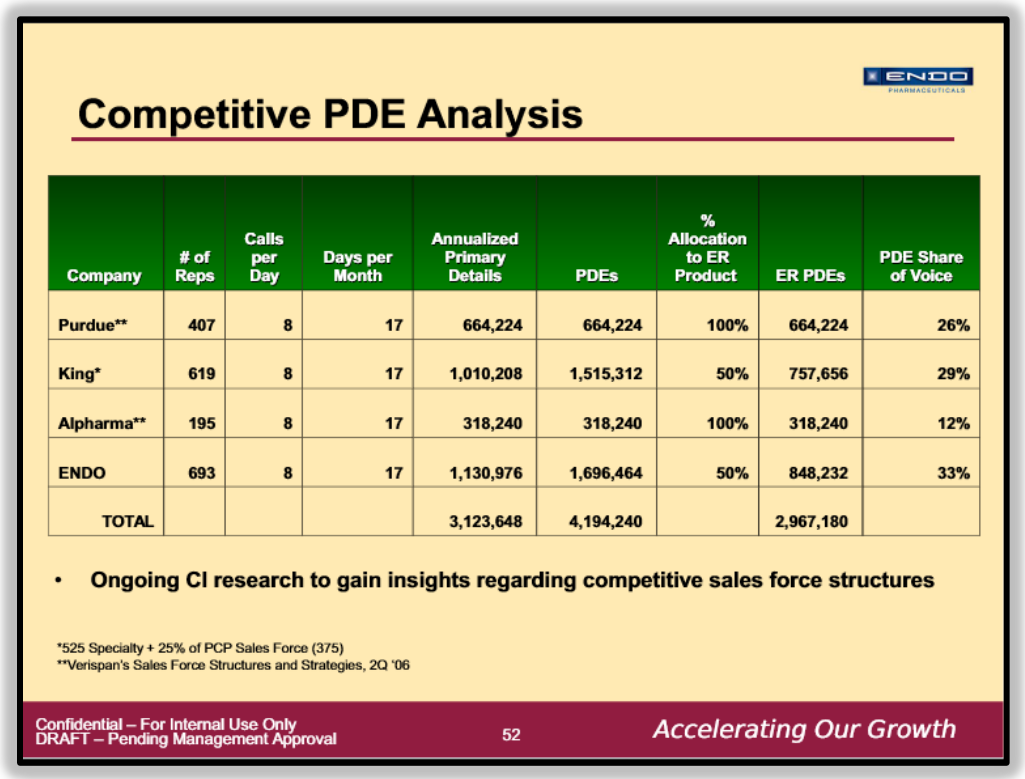


35. Endo acted upon and advanced these misleading concepts[23] instead of other (apparently) discarded recommendations by Endo's consultant that belie the company's aggressive marketing philosophy including an "Endo Drug Rehab Facility," covert company-sponsored demonstrations outside the offices of primary care physicians to demand greater access to opioids, a plan titled "Titration Phase Is On Us" in which the company would pay for a patient's first trial phase of Opana ER, a plan to package Opana ER with four increasing strengths included in a blister pack so that a patient could self-titrate "until the right dose is reached – all without office visits or multiple trips to the pharmacy," a program titled "Pain Pals" in which sales representatives would

[23] *Cf.* ENDO-OR-CID-00733299 (slides 35-36 of 120); ENT000070378, -388; ENDO-CHI_LIT-00548117; ENDO-CHI_LIT-547959 (slides 16-18, 21, 24 of 136); ENDO-CHI_LIT-00548031, -041, -046, -115, -117, -135, -136; ENDO-OR-CID-00596177 (slide 8 of 9).

meet with Opana ER patients to have coffee with them, and a program in which Endo would help health care providers "sort out any legal problems associated with the drug" if the provider was accused of wrongdoing.[24]

36. Endo aggressively executed its marketing strategy for its opioids and devoted substantial resources towards branded promotion to compete with Purdue. In a 2007 internal analysis, *Endo made more sales calls* (measured in units called primary detail equivalents (PDEs)) *than any other branded manufacturer*. According to its own analysis, Endo made 1,130,976 sales calls for extended release opioid products to providers nationwide, including in Tennessee.[25] Endo's numbers advantage for its sales consultants continued after 2007.[26]



Competitive PDE Analysis

Company	# of Reps	Calls per Day	Days per Month	Annualized Primary Details	PDEs	% Allocation to ER Product	ER PDEs	PDE Share of Voice
Purdue**	407	8	17	664,224	664,224	100%	664,224	26%
King*	619	8	17	1,010,208	1,515,312	50%	757,656	29%
Alpharma**	195	8	17	318,240	318,240	100%	318,240	12%
ENDO	693	8	17	1,130,976	1,696,464	50%	848,232	33%
TOTAL				3,123,648	4,194,240		2,967,180	

- **Ongoing CI research to gain insights regarding competitive sales force structures**

*525 Specialty + 25% of PCP Sales Force (375)
**Verispan's Sales Force Structures and Strategies, 2Q '06

Confidential – For Internal Use Only
DRAFT – Pending Management Approval
52
Accelerating Our Growth

[24] ENDO-OR-CID-00733299 (slides 74, 80, 81, 105, 110 of 120).

[25] ENDO-CHI_LIT-00541091.

[26] ENDO-OR-CID-00130718 (slide 71 of 151 stating "Endo will continue to have the largest sales force compared to key competitor sales organizations[.]").

37. In a summary of an audit of Endo's sales calls to health care providers, Opana ER was identified as having the "greatest share of voice among products in the marketplace."[27]

38. Endo used its sales force numbers advantage and instructed sales representatives to focus the "greatest call frequency of 3x-4x per month" on the highest prescribers of controlled substances,[28] and "[m]aintain 1x per week frequency on our top HCPs [health care provider] targets"[29]—including in Tennessee. As part of its overarching marketing objective, Endo sent targeted messages to these high- and mid-level prescribing health care providers.[30] Endo's marketing consultant told the company "[u]nderstanding *who* is generating significant profit, and profit growth, for OPANA ER and Endo provides additional insight[.]"[31]

39. Out of the approximately 27,000 providers nationwide that Endo targeted for Opana ER calls,[32] Endo reached at least 2,732 health care providers in Tennessee alone with Opana or Opana ER sales calls – over 10% of all targeted providers.[33] Between January 2008 and December 2016, the company made at least 109,801 sales calls in Tennessee[34] and continued to make sales calls for Opana ER in Tennessee until 2017.

40. Endo also routinely gave health care providers letter grades for their prescribing habits as a quick way for its sales representatives to identify who to prioritize for sales calls. Endo

---

27 ENDO-CHI_LIT-00547959 (slide 8 of 136).

28 ENDO-CHI_LIT-00541092; ENDO-CHI_LIT-00547007 (slide 23 of 52); *see also*, OPANA_ER_CALLS_ALL_STATES_2017019.

29 ENDO-OR-CID-1316607.

30 ENDO-CHI_LIT-00541068.

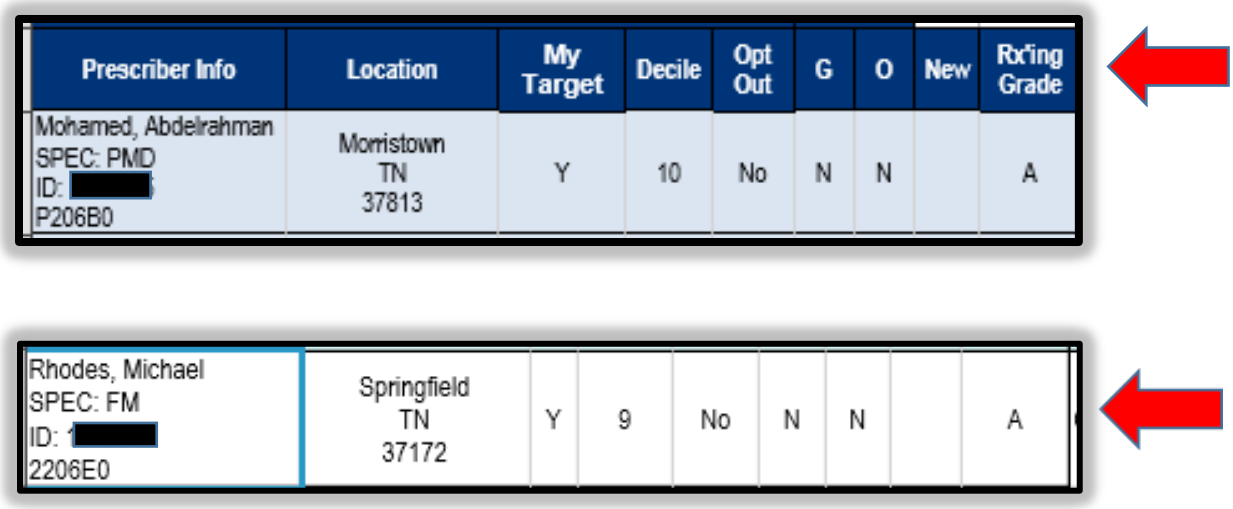
31 ENDO-OR-CID-00080698 (emphasis added).

32 ENDO-OR-CID-00094624.

33 ENDO-CHI_LIT-00543638.

34 OPANA_ER_CALLS_ALL_STATES_2017019.

gave some of the most notorious prescribers in Tennessee "A" letter grades for their unrestrained prescribing habits and encouraged its sales representatives to prioritize and make more frequent sales calls to them.[35] Two of these providers, who had disciplinary actions taken against their medical licenses or pleaded guilty to crimes related to their prescribing of controlled substances,[36] are shown below.



Prescriber Info	Location	My Target	Decile	Opt Out	G	O	New	Rx'ing Grade
Mohamed, Abdelrahman SPEC: PMD ID: [redacted] P206B0	Morristown TN 37813	Y	10	No	N	N		A
Rhodes, Michael SPEC: FM ID: [redacted] 2206E0	Springfield TN 37172	Y	9	No	N	N		A

41. Endo's sales calls paid off and yielded more prescriptions. Endo's chief marketing executive for Opana ER even stated that "OPANA ER is in a promotionally sensitive market"[37]—meaning that more sales calls generated more prescriptions in this market. Based on internal documents, Endo's return on investment for each sales call was projected as high as a 4:1 revenue-to-cost ratio.[38]

---

35 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab, row 7); ENDO-OR-CID-00781260 (Opana ER tab, row 144).

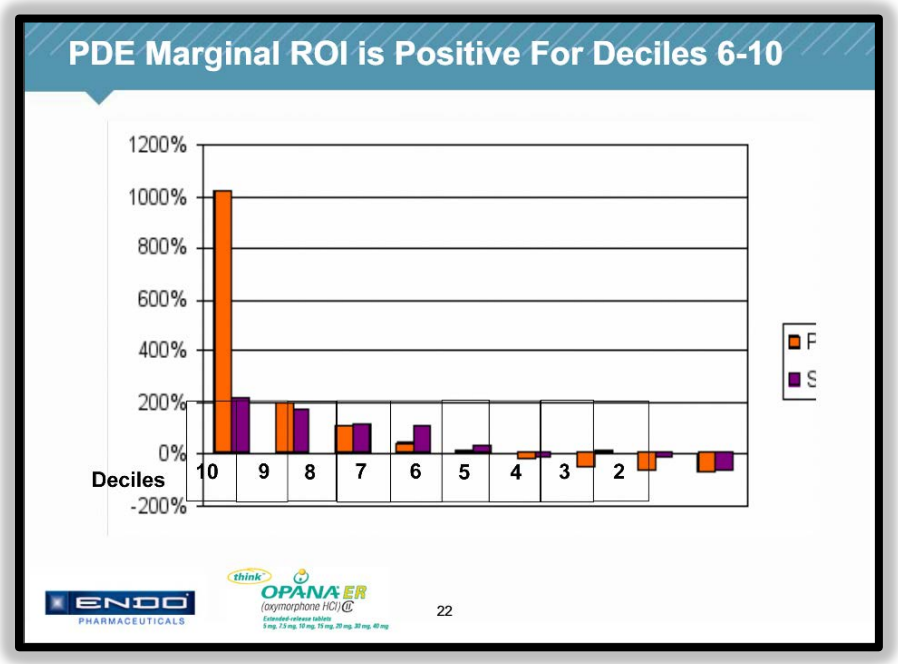
36 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_37647_092115; https://www.justice.gov/usao-edtn/pr/physician-owner-hnc-and-wife-sentenced-health-care-fraud-offenses-involving

37 ENDO-CHI_LIT-00550801.

38 ENDO-OR-CID-00098353.

42. Endo, like Purdue, also focused on health care providers who already prescribed significant quantities of its opioids and then told them to prescribe even more.[39] In a document titled "2009 Opana Brand Strategic Plan," Endo stated its intention to "increase the writing intensity of current OPANA ER prescribers and increase the product trial with mid-deciles prescribers via comprehensive and focused detailing and excellence in overall promotional execution."[40]

43. Endo focused on its highest prescribers (known as "decile 10 prescribers")[41] precisely because each additional sales call on one of its highest prescribers generated a significant return on Endo's investment. In an internal document, Endo showed that its return on investment for sales calls for the decile 10 prescribers was significantly higher than those who wrote fewer Opana ER prescriptions.[42]



39 *See, e.g.*, ENDO-OR-CID-01316607.

40 ENDO-CHI_LIT-00546435 (slide 2 of 86).

41 ENT000075911.

42 ENDO-CHI_LIT-00546435 (slide 22 of 86).

44. Endo had other proof that its sales calls worked to increase opioid sales. In an internal marketing document, Endo summarized the findings of a survey of doctors by stating, among other things:

- [f]eedback from MDs showed that lack of familiarity with OPANA ER *was highly correlated* with detailing efforts and relationship with the rep[;]
- [t]hose [providers] who have tried [Opana ER] *were largely persuaded to do so by a rep*, successful referrals[; and]
- Main messages are *resonating*.[43]

45. Like Purdue, Endo emphasized marketing to physician assistants (PAs) and nurse practitioners (NPs), who generally have less pain management expertise. Endo found that NPs and PAs were a "key driver of [sales] performance"[44] and pressed its sales force to consistently "focus on NPs and PAs."[45] Endo targeted NPs and PAs because it had data showing they were "3x times more responsive than MDs to details" and that "96% of prescriptions are written without physician consult (60% are for therapy initiation)."[46]

46. Endo identified, targeted, and cultivated the largest prescribers of Opana ER, called "high writers," in February 2008 as shown by the excerpt below:[47]

---

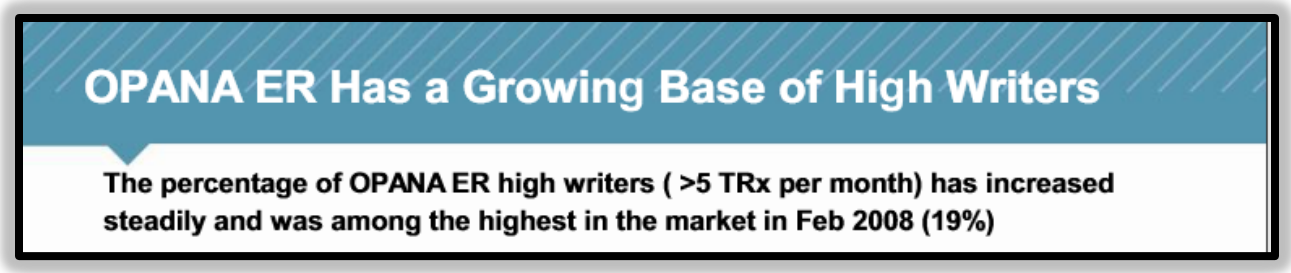
43 ENDO-OR-CID-00130750 (slide 103 of 151) (emphasis added).

44 ENDO-CHI_LIT-00555988 (slide 5 of 59); ENDO-CHI_LIT-00551611 (slide 3 of 41); ENDO-CHI_LIT-00541045; ENDO-OR-CID-00131019 (Opana ER tab).

45 ENDO-OR-CID-01316607.

46 ENDO-OR-CID-00223054; *see also* ENDO-CHI_LIT-00541045.

47 ENDO-CHI_LIT-00546434.



47. Endo not only significantly ramped up its marketing efforts to high writers in 2010 and 2011 in Tennessee, but also focused its marketing to these prescribers on *high strength doses* of Opana ER, which generated more money for Endo than low strength doses.

48. Endo's high strength doses of Opana ER were its 20, 30, and 40 mg tablets. One Opana ER 20 mg tablet taken every 12 hours equals 120 MMEs per day, a standardized unit of opioid potency.[48] This dosage is 30 MMEs *over* the 90 MME daily threshold that the 2016 CDC Guideline recommends providers should avoid or carefully justify.[49] One 40 mg Opana ER tablet taken every 12 hours equals 240 MMEs per day or *over twice* the CDC daily threshold.[50]

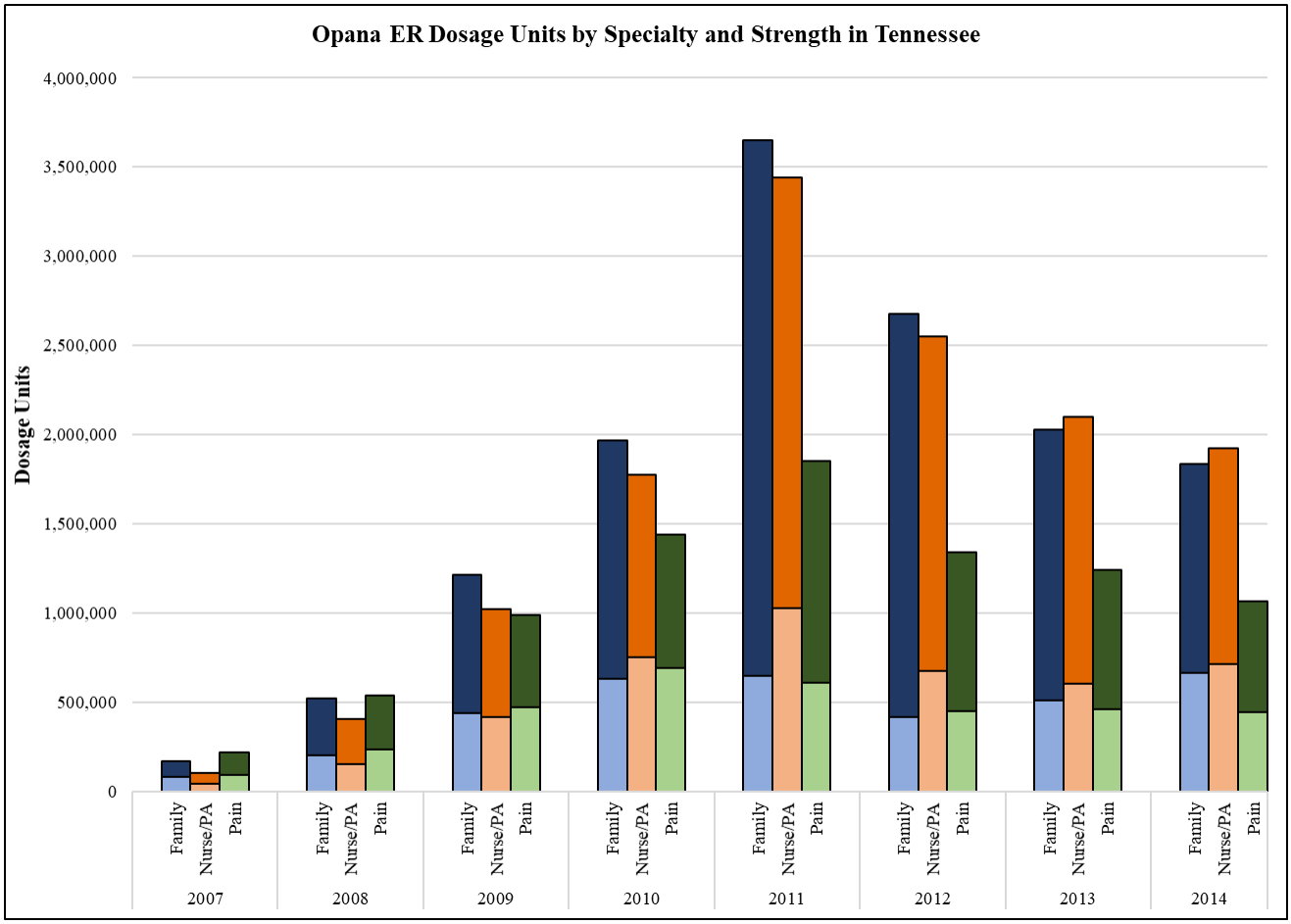
49. As shown by the chart below, Endo succeeded not only in getting its highest Tennessee writers of Opana ER to prescribe more, but in getting its highest Tennessee writers to prescribe more *high dose* (≥ 20 mg) Opana ER overall and in relation to other dosage strengths. As a result of Endo's marketing efforts, the absolute number and proportion of these high dose Opana ER prescriptions (shown in the darker color) went up dramatically in Tennessee—particularly for family doctors/general practitioners/internists, NPs, and PAs.[51]

[48] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf.

[49] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.

[50] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf.

[51] Chart created by Office of Tennessee Attorney General from ENDO-OR_MASS-CIDS-00000047.



50. Endo knew or should have known based on increases in its *sales of high strength doses of* Opana ER as well as increases *in the proportion* of its overall sales that significant abuse and/or diversion of Opana ER was taking place at the practices of its highest prescribers in Tennessee.

51. Endo's marketing went beyond sales calls to health care providers. Endo also communicated directly with consumers who had questions about Opana ER and other products[52] and used speakers programs in which Endo paid providers friendly to the company's messaging to speak about the purported safety, benefits, and efficacy of its opioid products including Opana

[52] ENDO-OR-CID-00117276 (Data tab).

ER to other providers.[53] Endo congratulated sales representatives in Tennessee for having "remarkable success using these programs," which resulted "in Opana ER market share actually exceeding OxyContin" in their respective territories.[54]

52. Ultimately, Endo relied heavily on continued users, which included addicted users, as a source of its business from the original formulation of Opana ER. Continued users represented 88% of Endo's total business from Opana ER.[55]

53. Endo's marketing worked exceptionally well in Tennessee, which had some of the highest-performing districts in the country for Opana and Opana ER prescriptions.[56] In 2009, for example, Tennessee had five of the top ten performing Opana ER sales representatives in the Southeast region.[57]

54. In August 2010, Purdue pulled the old formulation of OxyContin from the market and replaced it with a reformulated version that was purportedly less prone to *some* forms of abuse. Endo quickly recognized an opportunity and targeted pill mills in Tennessee. Endo knew those prescribers were looking for a replacement for OxyContin as their potent extended release opioid of choice. Endo knew that extended release opioids prescribed by these pill mills were being abused and diverted in large numbers.[58]

55. Endo's plan worked and the company congratulated itself and rewarded its sales representatives for their efforts. Sales districts in Tennessee experienced some of the highest levels

---

53 *See* ENDO-CHI_LIT-00546351; ENDO-OR-CID-00156466.

54 ENDO-OR-CID-00189258.

55 ENDO-CHI_LIT-00551611 (slide 31 (citing 88.3% continuation for source of business)).

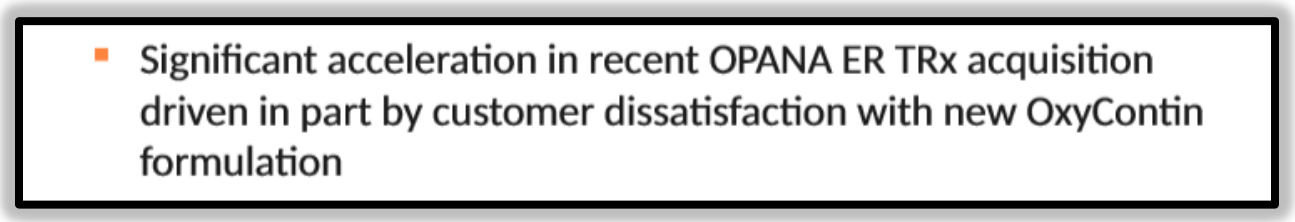
56 *See, e.g.*, ENDO-OR-CID-00733521 (Sheet2 tab); ENDO-OR-CID-00868428; ENDO-OR-CID-00225751 (Opana_Territory Tab); ENDO-CHI_LIT-00556194 (slide 14 of 73).

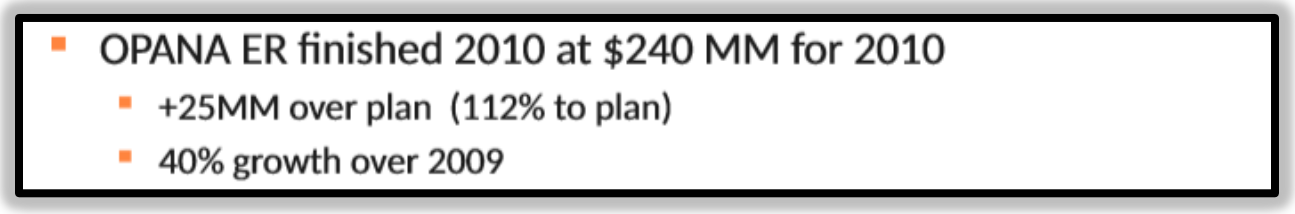
57 ENDO-OR-CID-00733517.

58 *See* ENDO-OR-CID-00428201; ENDO-OR-CID-00182442, -464, -487; ENDO-OR-CID-00584357 (slide 15 of 21).

of Opana ER sales growth following OxyContin's reformulation. Some Tennessee districts achieved the unthinkable—selling more than OxyContin, the market leader.[59]

56. Almost immediately after reformulated OxyContin's launch in August 2010, Endo confirmed that the significant increase in Opana ER prescriptions was "driven in part by customer dissatisfaction with [the] new OxyContin formulation" as shown by this excerpt in the executive summary of a quarterly business review in October 2010 that also referenced Opana ER finishing 2010 at "112% to plan" and with "40% growth over 2009."[60]





57. By October 2010, Endo had already recognized that Opana ER was experiencing "[a]ll-time highs in weekly [prescription] volume . . . due to current trends and patient dissatisfaction with new OxyContin formulation."[61]

---

59 ENDO-OR-CID-00079463 (emphasis added); *see also* ENDO-OR-CID-00225751 (Opana_Territory Tab); ENDO-OR-CID-00504468 (Opana_Territory Tab); ENDO-OR-CID-00431499.

60 ENDO-CHI_LIT-00545593 (slide 2 of 32).

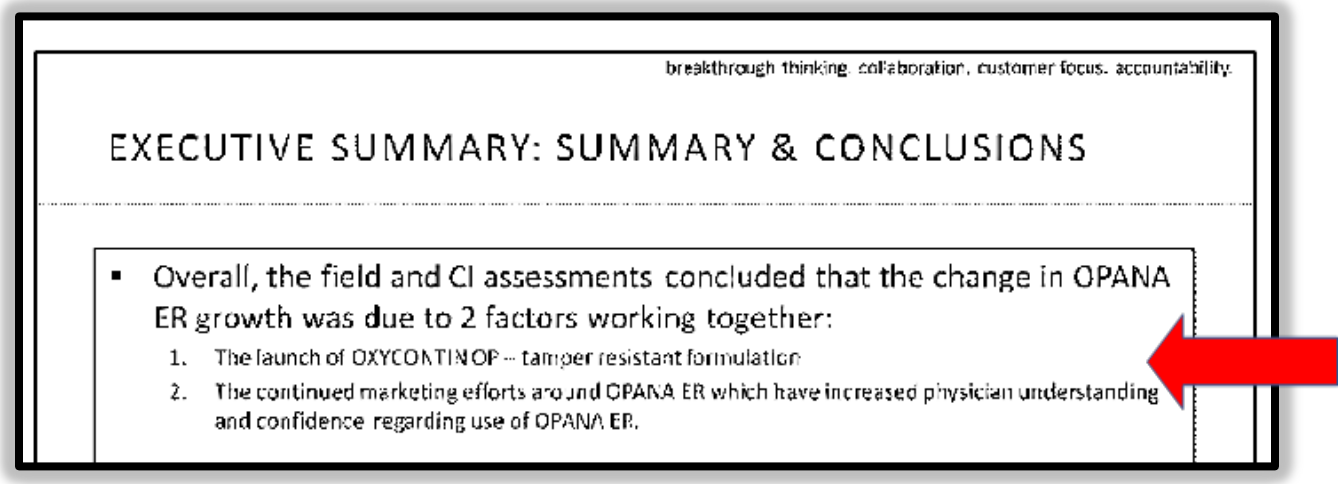
61 ENDO-OR-CID-00415894 (slide 11 of 34); *see also*, ENDO-OR-CID-01291894 (Response to District Manager Survey on January 4, 2011 "Is there causal effect between OXYCONTIN OP decline and OPANA ER growth? Yes, I have talked to me [sic] doctors through my district say that patients are stating that the new Oxy does not work. . .").

58. In a later internal document, Endo admitted that "*[t]he introduction of an abuse-deterrent formulation of OxyContin in August 2010 coincided with a documented increase in reported abuse rates of Opana ER*[.]"[62]

59. Endo continued to gather evidence that its Opana ER success, starting the fourth quarter of 2010, was due to its own marketing and that the company was capitalizing off of abusers and diverters who had previously used OxyContin. In an internal marketing report dated February 10, 2011 and titled "OPANA ER Growth Trends Issue – Market Research Final Report,",[63] Endo acknowledged the following (shown in the four excerpts below):

- Overall, the field and [competitor intelligence] assessments concluded that the change in OPANA ER growth was due to 2 factors working together:

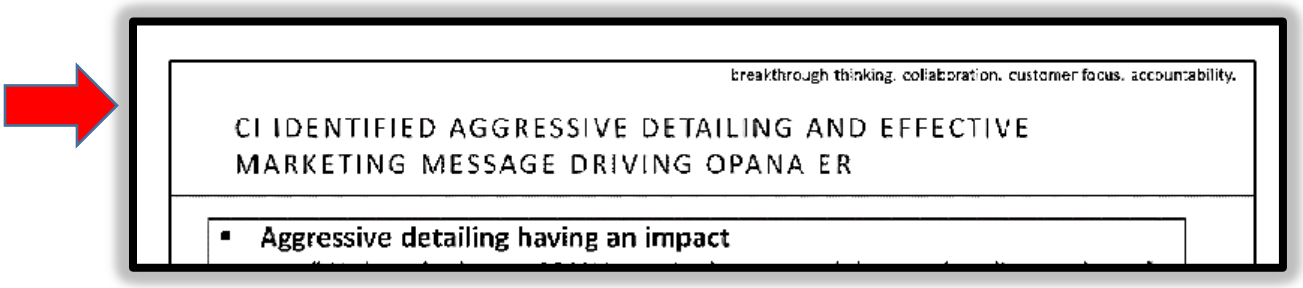
1. The launch of [reformulated OxyContin]–tamper resistant formulation [; and]
2. The continued marketing efforts around OPANA ER which have increased physician understanding and confidence regarding use of OPANA ER[.]



62 ENDO-OR-CID-00428201 (emphasis added).

63 ENDO-OR-CID-00182442, -487 (document is marked "draft" but was presented internally; *see* ENDO-OR-CID-00182441).

- [COMPETITOR INTELLIGENCE] IDENTIFIED AGGRESSIVE DETAILING AND EFFECTIVE MARKETING MESSAGE DRIVING OPANA ER[;][64]



- OPANA ER SHOWING MOST GAIN DURING OXYCONTIN LOSS[; and][65]

- [COMPETITOR INTELLIGENCE] IDENTIFIED ABUSE BEHAVIOR DRIVING DECLINE IN OXYCONTIN USE[.][66]

60. Likewise, in an internal document citing findings from an opioid abuse surveillance report in 2011, Endo confirmed that abuse of Opana ER was occurring with greater frequency than abuse of other opioids and had doubled from six months before, specifically identified "an increase

64 ENDO-OR-CID-00182442.

65 ENDO-OR-CID-00182463.

66 ENDO-OR-CID-00182464.

in abuse of oxymorphone (again, mostly OPANA ER) in relation to baseline of the year prior to release of reformulated OxyContin," and confirmed that *abuse of "oxymorphone, and OPANA ER increased more than 16 standard deviations above [that pre-reformulated OxyContin] baseline.*"[67]

61. In the same surveillance report, Endo also observed that:

> [B]eginning in Q2 2011 the proportion of posts in which OPANA was discussed became increasingly similar to the proportion of posts in which OxyContin was referenced. That said, while the proportion of authors and threads in which OxyContin was mentioned decreased incrementally over the 4 quarters of 2011, *the proportion of authors and threads in which OPANA was referenced remained comparatively consistent*. The steady decline in discussion around OxyContin may be related to a waning interest in the implications of the reformulated version of OxyContin introduced in 2010. Forum participants who discussed OPANA in 2011 regarded it as being powerful and having significant abuse potential. While several authors reported enjoying OPANA (often suggesting use of the product as a replacement to the reformulated OxyContin), others cautioned about the long-term consequences of abuse, such as overdose, addiction, increases in tolerance, and withdrawal . . . In conclusion the NAVIPPRO data for 2011 indicate that *abuse of OPANA ER continues to increase*. Overall, ASI-MV data revealed a shift (an increase) in the rate of abuse of OPANA ER throughout 2011 and in relation to baseline rates of abuse of OPANA ER observed among ASI-MV population over the 12 months *prior* to the release of reformulated OxyContin in August 2010. *The data from Internet Monitoring continues to suggest that recreational drug abusers are interested in the abuse of oxymorphone and posts regularly mentioned OPANA ER as a desirable replacement to the reformulated OxyContin. . .* [68]

62. Endo knew of numerous specific cases of individuals addicted to OxyContin switching to Opana ER as well. As one of many examples, Endo reported the following:

> OPER20110321 was a newspaper article received from a company representative concerning a 20-year-old male consumer who was taking OPANA ER. The consumer reported that he was initially addicted to OxyContin (oxycodone). After the crush resistant formulation of OxyContin was approved, the patient switched to OPANA ER and he became addicted to the medication.[69]

---

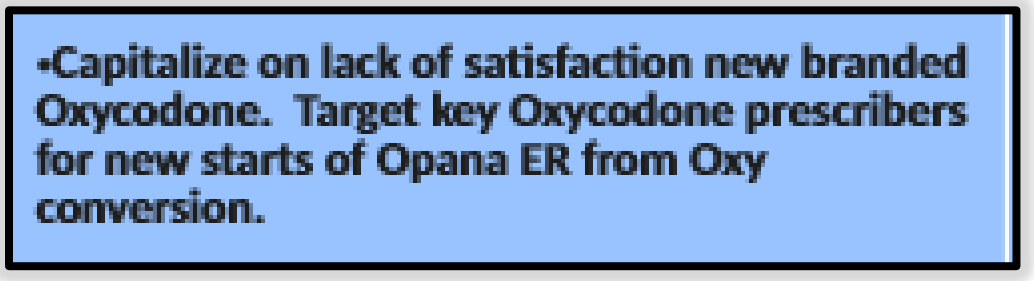
[67] ENDO-OR-CID-01228481 (emphasis added).

[68] ENDO-OR-CID-01228482, -483 (emphasis added).

[69] ENDO-OR-CID-01228477.

63. Despite knowing that individuals were switching from OxyContin to Opana ER as their abused or diverted opioid of choice, Endo decided to do nothing further about it, citing the launch of "the crush-resistant formulation" of Opana ER as "an important tool in the effort to mitigate the risk of these products."[70]

64. But worse than failing to act, Endo expressly sought to capitalize on this business opportunity. For example, in a 2011 Business Plan for Endo's Mid-Atlantic Business Unit, which included Tennessee, Endo stated as a "strategic imperative" its intention to "[c]apitalize on lack of satisfaction [with the] new branded Oxycodone. Target key Oxycodone prescribers for new starts of Opana ER from Oxy conversion."[71]



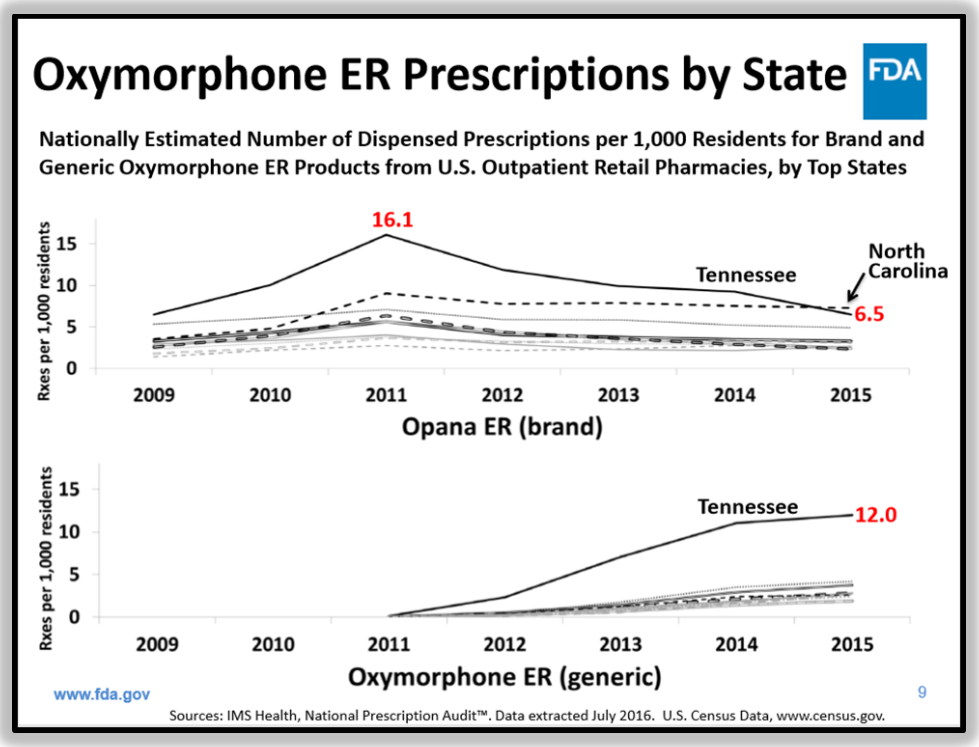
65. Endo benefitted disproportionally from Tennessee prescriptions of Opana ER. From 2009 to 2015, Endo's Opana ER sales in Tennessee were higher than any other state in the country, spiking significantly in 2011 following removal of the original formulation of OxyContin from the market.[72]

---

70 ENDO-OR-CID-01228460, -481, -485.

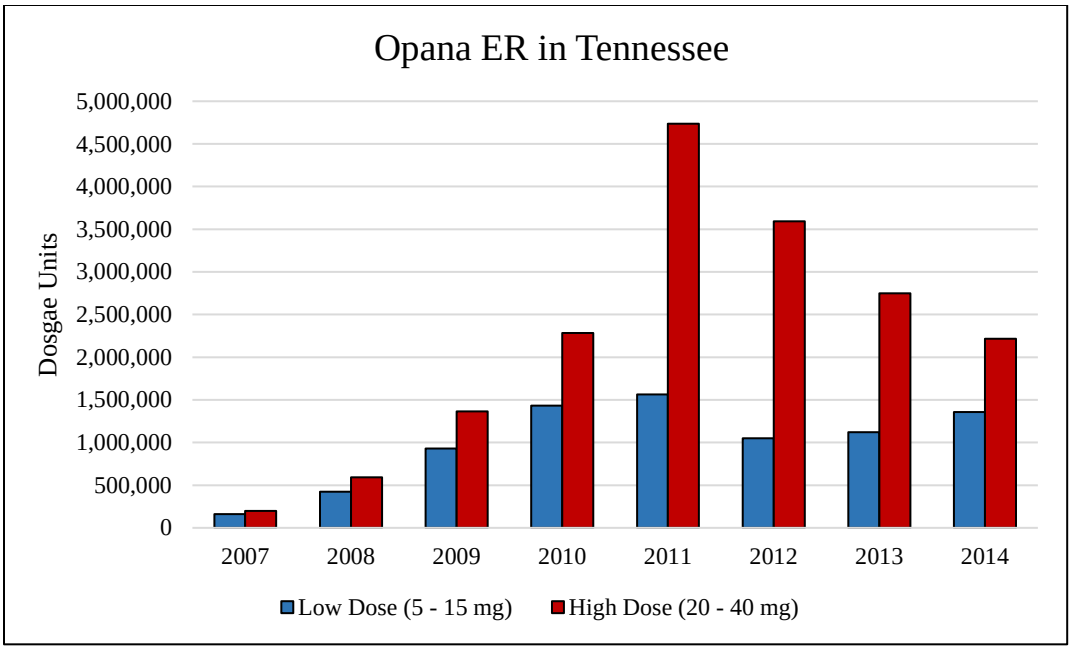
71 ENDO-OR-CID-00584357 (slide 15 of 21).

72 Corinne Woods, RPh, MPH, *Drug Utilization Patterns for Oxymorphone ER and Selected Opioid Analgesics, 2009-2015*, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, U.S. FOOD AND DRUG ADMINISTRATION (March 13-14, 2017), *available at* https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf (slides 8-9).



66. Opana ER's growth in Tennessee came overwhelmingly from high-dose prescriptions following removal of the old formulation of OxyContin from the market in August 2010 (as shown by the chart below)—yet another sign that Endo was deliberately capitalizing on individuals switching from OxyContin to Opana ER as their abused or diverted opioid of choice.[73]

[73] ENDO-OR_MASS_CIDS-00000047.



67. Endo's sales of Opana ER were especially high in East Tennessee. ***Between 2007 and 2014, Endo sold 916,513 more Opana ER tablets in Knoxville than in New York City, Los Angeles, and Chicago—combined***.[74] For context, Knoxville has an estimated population of 178,874 according to the 2010 U.S. Census, whereas the combined population of New York City, Los Angeles, and Chicago based on the same data is 14,663,352 or ***about 82 times larger***.[75]

68. In 2010, the North Knoxville territory was Endo's best[76] performing territory in the country and this success only continued. In a January 2011 spreadsheet that tracked the top-performing subdivisions of territories in the Mid-Atlantic region, an area that included West Virginia, Kentucky, North Carolina, Maryland, Delaware, and Virginia, Tennessee had the 1st, 3rd, 4th, and 5th highest performing subdivisions. North Knoxville, which was the subdivision with the most Opana ER prescriptions in the Mid-Atlantic region, had double the prescriptions of

---

74 *See* ENDO-OR_MASS_CIDS-00000047.

75 https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml.

76 ENDO-OR-CID-632354 (slide 8 of 27).

the next highest subdivision[77] and was one of the best-performing subdivisions for Endo in the United States.

69. The same January 2011 Endo spreadsheet also listed the top 100 prescribers of Opana ER in the Mid-Atlantic region—all of whom Endo gave "A" letter grades. Approximately one-third or 32 of the top 100 prescribers of Opana ER in the seven-state region were located in Tennessee. Of the 32 top 100 prescribers in Tennessee, 16 were concentrated in the Knoxville-area. [78]

70. Endo knew that the North Knoxville subdivision was one of its best performers. In a July 15, 2011 internal e-mail with a subject line of "Opana ER Milestone in Knoxville North," Endo's East Tennessee District Manager stated:

> We have become accustomed to seeing Opana ER milestones from the team of [three sales representatives] in the north Knoxville footprint.[79] They were the first team to go over 400 scripts in one week earlier this year and they have done again and again during P2. They set an all-time record again this week of 472 scripts which has become just-another-week expectation for this team.
>
> ***Something special occurred recently:*** **[The three sales representatives]** ***became the first team to grow their Opana ER market share over and above OxyContin! For the last two weeks in a row their 4 week share of the market reached 43.7%, exceeding the share of 41% for branded OxyContin!***
>
> When we launched Opana ER few [sic] years ago many people thought this day would never come and [the three sales representatives] have delivered the goods! See the report below and join me in congratulating this team for wowing us and continuing to show us what is possible.[80]

and attached the chart shown below:

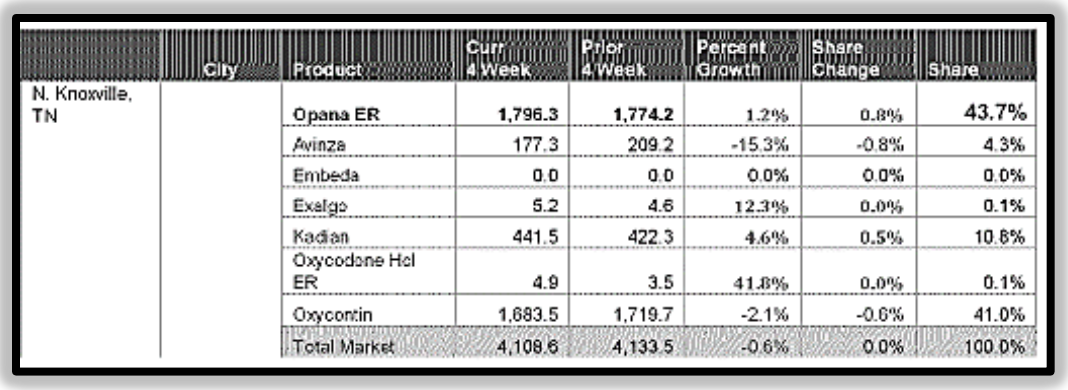
---

77 ENDO-OR-CID-00178528 (Top Footprints tab).

78 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

79 Footprint is Endo's name for a sales territory subdivision.

80 ENDO-OR-CID-00079463 (emphasis added); *see also* ENDO-OR-CID-00225751 (Opana_Territory Tab); ENDO-OR-CID-00504468 (Opana_Territory Tab); ENDO-OR-CID-00431499.



	City	Product	Curr 4 Week	Prior 4 Week	Percent Growth	Share Change	Share
N. Knoxville, TN		Opana ER	1,796.3	1,774.2	1.2%	0.8%	43.7%
		Avinza	177.3	209.2	-15.3%	-0.8%	4.3%
		Embeda	0.0	0.0	0.0%	0.0%	0.0%
		Exalgo	5.2	4.6	12.3%	0.0%	0.1%
		Kadian	441.5	422.3	4.6%	0.5%	10.8%
		Oxycodone Hcl ER	4.9	3.5	41.8%	0.0%	0.1%
		Oxycontin	1,683.5	1,719.7	-2.1%	-0.6%	41.0%
		Total Market	4,108.6	4,133.5	-0.6%	0.0%	100.0%

71. Likewise, in a 2011 Business Plan for the Mid-Atlantic Business Unit, Endo designated Knox, Anderson, and Union counties in Tennessee as "key" sales areas for Opana ER.[81]

72. For the third quarter of 2012, the North Knoxville territory had the most Opana ER sales in the country with 2,812 prescriptions—a figure that dwarfed the next best performing territory.[82]

73. Unsurprisingly, Endo made significantly more sales calls to Knoxville and East Tennessee than anywhere else in the state. Endo's sales representatives made more sales calls between January 2008 and May 2010 to providers in Knoxville, which had a population of approximately 178,874 according to the 2010 census, than to providers in the three other largest cities in Tennessee— Memphis (population 646,889), Nashville (population 601,222), and Chattanooga (population 167,674)—*combined*.[83] Endo made 1,641 sales calls to Morristown, over *600 more* than Endo made to Memphis prescribers, a city with *22 times* its population.[84]

---

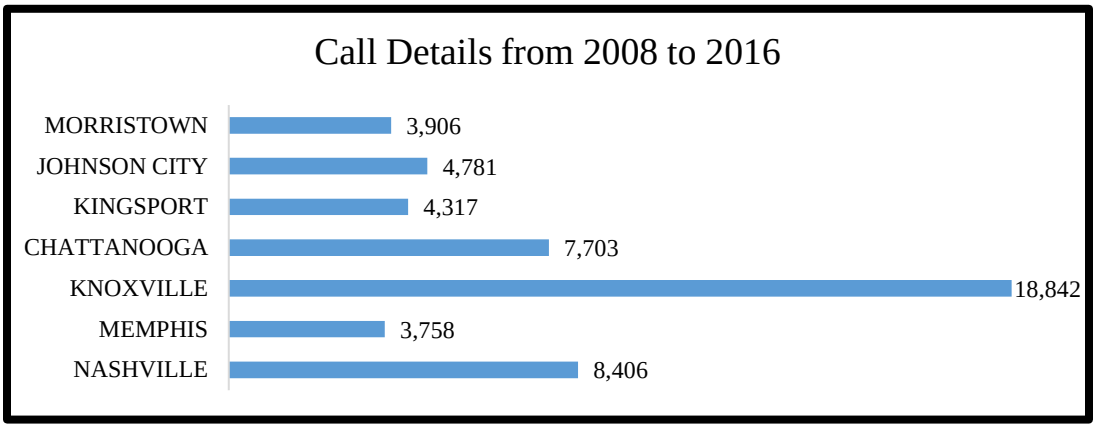
81 ENDO-OR-CID-00584357 (slide 9 of 21).

82 ENDO-OR-CID-00486812 (OPANA ER_Territory tab, row 96).

83 OPANA_ER_CALLS_ALL_STATEs_2017019 (showing 7,207 sales calls in Knoxville, 3,782 in Nashville, 1,011 in Memphis, and 2,346 in Chattanooga between 1/08 and 5/10).

84 *Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2017*, U.S. CENSUS BUREAU *available at* https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk (showing 646,889 residents of Memphis and 29,137 residents of Morristown).

74. The disproportionate number of sales calls directed to Knoxville, Morristown and other cities and towns in East Tennessee continued between 2008 and 2016 as shown by the chart below:



75. Endo's sales of the original formulation of Opana ER were booming, but Endo knew that its financial success would not last because generic versions of Opana ER were set to come onto the market. Endo continued to follow Purdue's playbook and prepared to launch a reformulated version of Opana ER to maintain its revenue stream.

Opana ER (reformulated version)

76. Manufacturers of brand-named drugs like Endo often work to delay or thwart the entry of generic competitors. The entry of a generic competitor for a brand-named drug usually means that the manufacturer's revenue stream from that brand-named drug is significantly reduced.

77. To get approval from the U.S. Food and Drug Administration, a generic manufacturer must show, among other things, that the active ingredient in its generic version is bio-equivalent to the brand-named drug through an Abbreviated New Drug Application (ANDA). In contrast, a brand-named drug must receive approval by the FDA through a more rigorous New Drug Application (NDA), which can be supplemented through a Supplemental New Drug

Application (sNDA). Partly because the approval and development processes are much less costly and there is no longer patent exclusivity, generic drugs are usually priced to be much less expensive than their branded counterpart.

78. An ANDA ties the generic drug to a brand-named drug's NDA, so if the brand-named drug version with the NDA is removed from the market because of safety concerns, so too is any corresponding generic. Purdue successfully obtained an sNDA for a reformulated OxyContin that had modest abuse deterrence characteristics, thereby extending its patent protection, and succeeded in getting the FDA to remove its old formulation with the old NDA from the market. Removal of the old OxyContin formulation had the effect of eliminating the generic versions of it as well.

79. Endo prepared for the arrival of generic Opana ER and decided to follow in Purdue's footsteps for thwarting its generic OxyContin competitors. On July 7, 2010, Endo submitted a sNDA for a "reformulated" Opana ER that it claimed was designed to be crush resistant[85] and that would have potentially extended its patent protection from generics until July 10, 2029.[86]

80. Endo was keenly aware of the risk to its market share if the application for the reformulation was not approved. In 2010, Endo's Senior Product Manager for the Opana brand

---

[85] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000MedR.pdf (p. 2); *see also*, Ellen Fields, MD, MPH, *Regulatory History of Opana ER*, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, U.S. FOOD AND DRUG ADMINISTRATION, (March 13-14, 2017), *available at* https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf (slide 9).

[86] *See* https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=201655&Appl_type=N (Orange Book entry showing the drug substance patent that is listed only for the new formulation of Opana ER, patent number 7,851,482, expires on July 10, 2029).

stated in an internal document that "[s]ignificant erosion of oxymorphone franchise to generics is likely if [the application for reformulated Opana ER] is not filed and approved in a timely manner."[87]

81. In December 2010, the FDA approved two ANDAs for generic versions of the original Opana ER submitted by Impax Laboratories and Actavis South Atlantic. Endo bought some time with one of these generic manufacturers, Impax, through a patent license agreement that blocked Impax from selling its generic Opana ER until January 1, 2013.[88]

82. On January 7, 2011, an FDA Advisory Panel evaluating Endo's sNDA for the reformulated Opana ER recognized that it was bio-equivalent to the original formulation and remained susceptible to abuse, but recommended that the product label, if approved, not contain any reference to crush resistance or abuse deterrence. The Advisory Panel stated:

- The improvement for crushing was only "minimal[;]"[89]
- "Of more concern, when chewed … the new formulation essentially dose dumps like an immediate-release formulation. While the label and MedGuide would certainly carry warnings against chewing, *some concern exists that any language in the label noting the reduced crushability of this formulation could be misleading and result in health care practitioners or patients thinking that is safer than the old formulation, and that it is safe to chew the product*; or that it is safe to give the new product to a cognitively impaired patient who may chew the product if not adequately supervised[;]"[90]

---

87 ENDO-CHI_LIT-00546621 (slide 3 of 41).

88 FDA Resp., *Endo Pharm. Inc. v. U.S. Food and Drug Admin.*, Case No. 1:12-cv-01936-RBW (D.D.C. Dec. 3, 2012) (Doc. 9, p. 4) *available at* https://www.fdanews.com/ext/resources/files/archives/1/12/12-4-12-Lawsuit2.pdf.

89 *Summary Review for Regulatory Action for Application Number 201655Org1s000*, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION, 3, (Jan. 7, 2011), *available at* www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000MedR.pdf.

90 *Id*. (emphasis added).

- "As demonstrated by significant increase in peak plasma levels compared to intact product, *extended release characteristics of [reformulated Opana ER] were defeated when chewed and consumed*[;]"[91]

- "[FDA doctor advisor] notes in her review that [reformulated Opana ER] *does not show good resistance to tampering employed by recreational or experienced abusers, as evidenced by a 60% increase in the dissolution in one hour for tablets* . . . compared to intact tablets[;]"[92]

- "[Reformulated Opana ER] provides *limited resistance to physical and chemical manipulation for abuse*. [Reformulated Opana ER's] extended release mechanism can be overcome by cutting, chewing, or grinding. Intake of [reformulated Opana ER] with food or alcohol increases blood levels of oxymorphone. [Reformulated Opana ER] tablets provide some resistance to crushing[;]"[93]

- "*An in vitro study conducted by the Sponsor shows that it might be easier to prepare a solution for injection when using [reformulated Opana ER] than when using OPANA ER*. Exposure of crushed [Reformulated Opana ER] 40 mg tablet . . . of the label claim of extracted oxymorphone HCL. However, the bench top manipulation study, Study EN3288-901 showed that both formulations behaved similarly[;]"[94]

- "Clinical abuse liability study EN3288-109 demonstrates that mastication of [reformulated Opana ER] compromises the controlled release mechanism of [reformulated Opana ER; and]"[95]

- that the Controlled Substance Staff team recommends that the label not include language asserting crush resistance.[96]

83. As the Advisory Panel noted, Endo's own studies that it submitted to the FDA showed that the reformulated Opana ER (identified above and below as EN3288) could still be

---

91 *Id.* at 8 (emphasis added).

92 *Id.* (emphasis added).

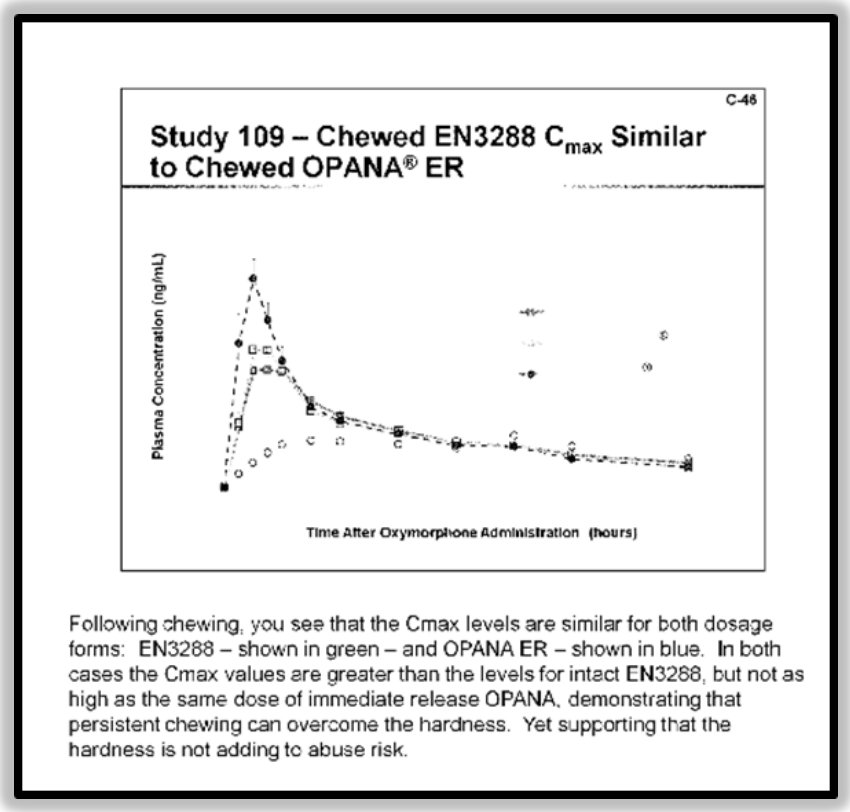
93 *Id.* at 11 (emphasis added).

94 *Id.* (emphasis added).

95 *Id.* at 12.

96 *Id.*

ground and chewed[97] and dose-dumped just like the old version (identified below as Opana ER) as shown by the chart summarizing data from Endo's Study 109:



84. Endo knew that it had a weak case for abuse deterrent labeling and contemplated funding a new study seeking to differentiate the reformulated Opana ER from the original version. But fearing the results of such a study, Endo eventually rejected the idea. When Endo's Director of Project Management proposed an intranasal abuse study to Endo's Research and Development Department, she was "met with strong resistance."[98] Likewise, in an October 10, 2011 e-mail titled "Differentiation Opportunities for [Reformulated Opana ER]," Endo's Director of Project Management notified Endo's business partner, elaborated on Endo's fears and stated:[99]

---

97 *Id.* at 13; ENDO-OR-CID-00023768.

98 ENDO-OR-CID-00351931.

99 ENDO-OR-CID-00351932 (emphasis added).

> o We fear that there will be little differentiation between Opana CRF and Opana ER in an intranasal abuse study. We already demonstrated that there was little difference between Opana CRF and Opana ER in Study 108 when both products were ground. FDA deemed that there was no difference and this contributed to their statement that we had not shown an incremental benefit. The chewing study (109) showed the same thing – no real difference – which the FDA used to claim no incremental benefit. We cannot determine any valid scientific reason why the intranasal route would be any different. We would expect PK to be comparable and therefore liking, also. This is what we need your and Ed Seller's input in helping us to understand. (By the way we have established contact and I will set something up soon).
>
> o If the intranasal abuse liability study fails, then we would have yet a third study which shows no real incremental difference between old and new.

Later in the e-mail, Endo's Director of Project Management stated, among other things:[100]

> I am sharing all of this with you so that you have time to think through our concerns and provide evidence as to why they are not as big as we think they are. We have a $400MM asset in Opana ER/CRF, and our first priority must be "do no harm". I hope this information will help us have a productive discussion next week.

85. Despite enjoying record profits from the original formulation of Opana ER in 2011, Endo actively worked to blunt the impact of its generic competitor, Actavis. Actavis was set to launch generic 7.5 mg and 15 mg versions of Opana ER based on the old formulation and did so on July 15, 2011.[101] Endo preemptively removed these strengths of its Opana ER from the market by May 1, 2011.[102]

86. Later that year, on December 9, 2011, the FDA approved the reformulated Opana ER,[103] but "determined that the drug did not meet the agency's standards for being considered abuse-deterrent and therefore declined Endo's request to include a description of abuse-deterrent

---

100 ENDO-OR-CID-00351932.

101 *See* ENDO-OR-CID-00378718 (slide 19 of 74).

102 ENDO-OR-CID-00150241, -242.

103 *Approval Package for Application No. 201655Org1s000*, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION (Dec. 9, 2011), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000Approv.pdf.

properties in product labeling."[104] The FDA did not allow Endo to make a crush resistance claim and noted:

> While the new formulation has demonstrated a *minimal* improvement in resistance to tampering by crushing, thereby limiting the likelihood of abuse by crushing followed by ingestion, and by insufflation (snorting) to some degree, ***it can still be … cut … rendering it readily abusable by ingestion and intravenous injection***, and possibly still by insufflation; although whether … tablets can be snorted was not studied. ***Of more concern, when chewed … the new formulation essentially dose dumps like an immediate-release formulation***.[105]

87. Increasingly desperate to thwart its generic competitors, Endo resorted to filing a Citizen Petition[106] with the FDA on August 13, 2012, falsely claiming that it had removed the old, crushable version of Opana ER from the market for "safety" reasons and requested that the FDA suspend and withdraw the approval of any generic Opana ER for the old formulation.[107]

88. Concerning the old formulation of Opana ER, Endo represented in the Citizen Petition:

> Endo discontinued Opana® ER (NDA No. 021610) for reasons of safety. While Opana® ER is safe and effective when taken as prescribed, it was nevertheless subject to abuse, misuse and diversion. *And recent data and reports suggest that rates of abuse, misuse, and diversion of opioid analgesics, such as Opana® ER, continue to rise. Notably, abuse of extended release oxymorphone has risen by approximately 139% since the introduction of abuse-deterrent OxyContin (oxycodone HCl) on the market in 2010.* This suggests that, among intentional abusers of opioids, the difficulty in abusing the new formulation of OxyContin has driven abusers to formulations that lack similar abuse-deterrent technologies. The increase in Opana® ER abuse rates are attributed to the ease of defeating the

---

[104] *Oxymorphone (marketed as Opana ER) Information*, U.S. FOOD AND DRUG ADMINISTRATION, *available at* https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm562339.htm.

[105] www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (pp. 3–4) (emphasis added); *see also*, ENDO-OR-CID-00073848 (n. 5).

[106] FDA regulations permit any "interested person" to "petition the [FDA] Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. §§ 10.25(a), 10.30.

[107] Endo Citizen Pet. at 1, *available at* https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2012/September/Endo%20Pharmaceuticals%20Opana%20ER%20citizen%20petition%20081320012.pdf (Note: Letter lists August 10, 2012 date, but file stamp indicates it was received by FDA on August 13, 2012).

> extended release properties of Opana® ER. The recent spike in Opana® ER abuse has been accompanied by a rise in overdoses from Opana® ER. Non-crush-resistant formulations are becoming increasingly attractive targets of abuse and diversion.[108]

89. Endo's conveniently-timed admission was not made public before Endo stopped marketing the original formulation of Opana ER *just three months earlier* and certainly not while Endo still had protection from generic competitors for Opana ER. Tellingly, when Endo introduced the new Opana ER formulation in December 2011, it did not recall the old formulation from the market, but instead continued to market the original formulation *until May 31, 2012*[109] *and sell it until at least until the week of June 8, 2012*.[110]

90. Endo acted in other ways to attribute additional bad outcomes to the old formulation of Opana ER and not the reformulated version. During the time that both the original and reformulated Opana ER were on the market and Endo was trying to position the reformulated version as safer than the old formulation, the company improperly coded *all* adverse event reports that it received that did not specify a formulation *as relating to the old formulation*.[111] While Endo buried reference to its default coding in a filing with the FDA,[112] the coding had the effect of attributing none of the adverse events to the reformulated version of Opana ER at the time when that product was first being launched.

---

[108] Endo Citizen Pet. at 7-8 (emphasis added).

[109] FDA's Mem. in Support of Federal Defs. Mot. to Dismiss, *Endo. Pharm., Inc. v. U.S. Food and Drug Admin.*, No. 12-1936 (RBW), 2012 WL 10731533, *1 (D.D.C. Dec. 9, 2012); Janet Woodcock, M.D., Docket No. FDA-2012-P-0895, CENTER FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMINISTRATION, 3 (May 10, 2013) (hereinafter FDA Endo Citizen Pet. Denial) *available at* https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/May/FDA_CDER_Final_RespEndo_Pharmaceuticals_Inc_Petition_Denial.pdf.

[110] ENDO-OR-CID-380237 (slides 11–12 of 155).

[111] ENDO-OR-CID-00918144.

[112] ENDO-OR-CID-00844091, -092.

91. Endo continued to position the reformulated Opana ER as safer than the original despite knowledge that abuse by chewing and cutting followed by intravenous injection was spiking, which the FDA's December 9, 2011 sNDA application response foretold.

92. For example, on August 3, 2012, Endo was notified by a pharmacist in [redacted], North Carolina of a 29-year-old female who admitted to melting and injecting the reformulated Opana ER, and who had a low blood platelet count consistent with a rare blood disorder known as thrombotic thrombocytopenic purpura (TTP).[113]

93. Less than two weeks later, Endo was notified of a larger cluster of individuals in East Tennessee who also developed TTP or a TTP-like disorder by injecting the reformulated Opana ER and then sharing intravenous needles.[114] By that time, Endo was well aware that East Tennessee was a hot bed for abuse and diversion of opioids.

94. Robert Barto, Endo's Vice President for Regulatory Affairs, knew about the Tennessee TTP cluster[115] and *knew specifically that several of the individuals injected the material after initially cutting the tablets into 5 or 10 pieces*.[116] The following is an excerpt from a prepared summary Mr. Barto submitted to the FDA on August 22, 2012:[117]

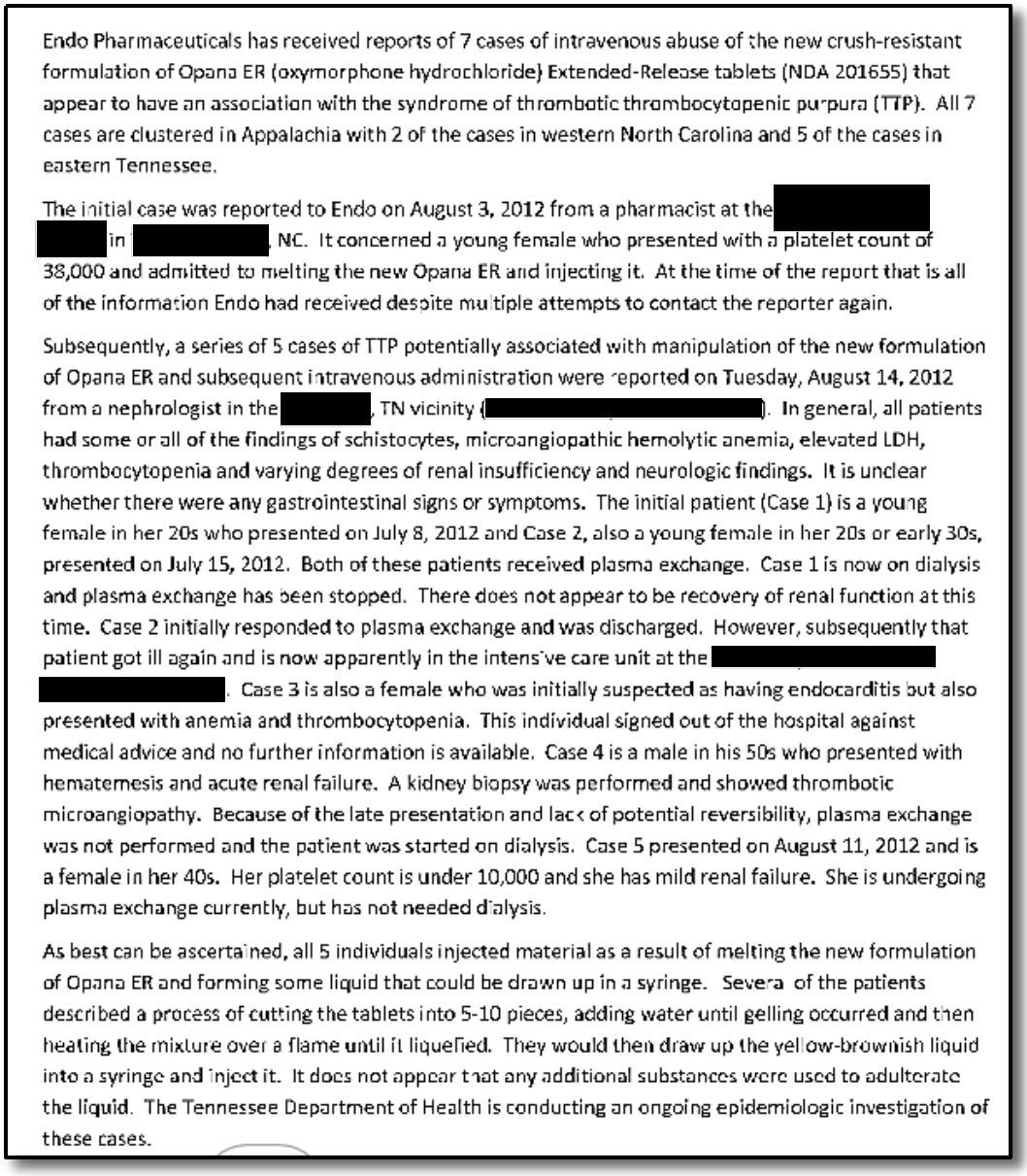
[113] ENDO-OR-CID-01026817 (slide 5 of 13).

[114] ENDO-OR-CID-00838559 (slide 6 of 13); ENDO-OR-CID-01222027.

[115] ENDO-OR-CID-01178154.

[116] ENDO-OR-CID-01238159; ENDO-OR-CID-01074604.

[117] ENDO-OR-CID-01238159.



Endo Pharmaceuticals has received reports of 7 cases of intravenous abuse of the new crush-resistant formulation of Opana ER (oxymorphone hydrochloride) Extended-Release tablets (NDA 201655) that appear to have an association with the syndrome of thrombotic thrombocytopenic purpura (TTP). All 7 cases are clustered in Appalachia with 2 of the cases in western North Carolina and 5 of the cases in eastern Tennessee.

The initial case was reported to Endo on August 3, 2012 from a pharmacist at the [redacted] in [redacted], NC. It concerned a young female who presented with a platelet count of 38,000 and admitted to melting the new Opana ER and injecting it. At the time of the report that is all of the information Endo had received despite multiple attempts to contact the reporter again.

Subsequently, a series of 5 cases of TTP potentially associated with manipulation of the new formulation of Opana ER and subsequent intravenous administration were reported on Tuesday, August 14, 2012 from a nephrologist in the [redacted], TN vicinity ([redacted]). In general, all patients had some or all of the findings of schistocytes, microangiopathic hemolytic anemia, elevated LDH, thrombocytopenia and varying degrees of renal insufficiency and neurologic findings. It is unclear whether there were any gastrointestinal signs or symptoms. The initial patient (Case 1) is a young female in her 20s who presented on July 8, 2012 and Case 2, also a young female in her 20s or early 30s, presented on July 15, 2012. Both of these patients received plasma exchange. Case 1 is now on dialysis and plasma exchange has been stopped. There does not appear to be recovery of renal function at this time. Case 2 initially responded to plasma exchange and was discharged. However, subsequently that patient got ill again and is now apparently in the intensive care unit at the [redacted]. Case 3 is also a female who was initially suspected as having endocarditis but also presented with anemia and thrombocytopenia. This individual signed out of the hospital against medical advice and no further information is available. Case 4 is a male in his 50s who presented with hematemesis and acute renal failure. A kidney biopsy was performed and showed thrombotic microangiopathy. Because of the late presentation and lack of potential reversibility, plasma exchange was not performed and the patient was started on dialysis. Case 5 presented on August 11, 2012 and is a female in her 40s. Her platelet count is under 10,000 and she has mild renal failure. She is undergoing plasma exchange currently, but has not needed dialysis.

As best can be ascertained, all 5 individuals injected material as a result of melting the new formulation of Opana ER and forming some liquid that could be drawn up in a syringe. Several of the patients described a process of cutting the tablets into 5-10 pieces, adding water until gelling occurred and then heating the mixture over a flame until it liquefied. They would then draw up the yellow-brownish liquid into a syringe and inject it. It does not appear that any additional substances were used to adulterate the liquid. The Tennessee Department of Health is conducting an ongoing epidemiologic investigation of these cases.

95. Instead of addressing the problem, Endo strived to minimize it, saying it was confined to a specific region, and doubled-down on the (phantom) public health benefits of the reformulated version of Opana ER. In an internal document prepared to deflect questions about the cluster, Endo stated:

> New data regarding injection of reformulated Opana ER suggests that the observed higher abuse via this ROA [(route of administration)] may be due to a regional pattern of abuse in that a large percentage of the cases were from the state of Tennessee compared to other states with treatment center locations within the ASI-

> MV [(Addiction Severity Index-Multimedia Version)] network. Prescription opioid abuse as observed via the ASI-MV has historically been high in the state of Tennessee relative to other states (46.6% versus 19.4). In all other states that contributed data to the ASI-MV during the study time period, the percentage of individuals who reported injection of reformulated Opana ER (24.4%) was similar to that of original Opana ER (20.0%) and higher than low-dose generic ER oxymorphone products (16.7%). Further, in contrast to the pattern observed among abusers of reformulated Opana ER in Tennessee, oral abuse of reformulated Opana ER (59.3%) was the predominant route of administration observed among individuals who reported abuse of the product in all other ASI-MV states with snorting (20.9%) the less frequently reported route of administration for the product.
>
> While continuing to investigate the information concerning cases of thrombotic thrombocytopenic purpura (TTP) in Tennessee, Endo reaffirms that *these data indicate that the crush-resistant formulation of Opana ER is having the intended effect of reducing overall rates of abuse and abuse via the primary route of abuse – crushing and snorting – of crushable oxymorphone HCl ER.*[118]

96. Shortly thereafter, Endo confirmed it knew that the inactive component to the reformulated Opana ER was likely the cause of the TTP cluster. On August 23, 2012, Endo admitted the following in an internal document:

> Of note, there is some evidence from the non-clinical literature to suggest that high molecular weight polyethylene oxide (PEO) may cause hemolytic anemia and thrombocytopenia when high doses were administered parentally to animals.
>
> PEO is the inactive ingredient in Opana ER CRF [Crush Resistant Formulation] that causes gelling upon exposure to water.[119]

97. News of the TTP cluster was widely known at Endo, but once again Endo devoted more attention to public relations, not public health. As before, Endo directed its promotional

---

[118] ENDO-OR-CID-00428224–25 (emphasis in original) (Endo was responding to Impax's assertion that "Finally, Endo's own data showing a marked increase of abuse through intravenous administration, coupled with reported cases of illnesses related to such intravenous abuse, raises an entirely new public safety concern specific to the reformulated product. Thus once again, Endo has failed to show that its [reformulated Opana ER] product is any 'more safe' than [the original formulation of Opana ER] or its generic equivalents[;]" *see also*, ENDO-OR-CID-00071953.

[119] ENDO-OR-CID-00918345 (slide 32 of 48); *see also*, ENDO-OR-CID-00043559.

speakers nationwide to respond to potential questions about TTP from health care providers,[120] but did not back away from its claims that the reformulated version was safer than the original.

98. On October 1, 2012, Endo's Vice President of Pharmacovigilance and Risk Management directly interviewed a female intravenous user of Opana ER from the Tennessee TTP or TTP-like cluster by phone.[121] From this interview, Endo knew that she had repeatedly taken high-dose Opana ER intravenously by cutting the tablet with scissors and then placing it in a spoon with some water before drawing it up into a needle.[122] As testament to the potency of high-dose Opana ER, Endo knew "it was typical to get 5 'hits' out of a single tablet this way."[123] Endo also knew that the cut Opana ER tablet did not gel when placed in water.[124]

99. By October 23, 2012, Endo knew of 12 individuals with confirmed TTP and five other potential cases in Tennessee.[125] Endo continued to track the number of instances of TTP as an agenda item for its Opana ER Risk Management Team.[126]

100. As news of the TTP cluster spread and the January 1, 2013 launch date for Impax's generic version of Opana ER approached, Endo's desperation manifested through a burst of litigation. On November 30, 2012, Endo sued the FDA seeking an injunction to force the FDA's decision on its Citizen Petition by December 31, 2012[127] even though by law the FDA has up to 270 days to complete a review of a citizen petition.

---

120 ENDO-OR-CID-00431694.

121 ENDO-OR-CID-00516055; ENDO-OR-CID-00601668.

122 ENDO-OR-CID-00516055.

123 ENDO-OR-CID-00516055.

124 ENDO-OR-CID-00516055.

125 ENDO-OR-CID-00070275.

126 ENDO-OR-CID-00148153.

127 Compl., *Endo Pharm. Inc. v. U.S. Food & Drug Admin.*, Case No. 1:12-cv-01936-RBW, 2012 WL 10901834 (D.D.C. Nov. 30, 2012).

101. Endo then sued Actavis on December 11, 2012, alleging that Actavis's marketing, which referenced being a generic of Opana ER, violated federal and state laws for false advertising and unfair competition.[128] Endo's hypocrisy did not go unnoticed. As Actavis argued and the federal court observed, Endo "simultaneously marketed the two versions [of Opana ER] for some months, but of course does not accuse *itself* of confusing physicians."[129]

102. Meanwhile in Endo's lawsuit against the FDA, Endo revealed its *true* motivation for the burst of litigation in a sworn declaration from its Chief Operating Officer. The December 18, 2012 declaration stated that the FDA's failure to grant Endo's Citizen Petition *would result in a $135 million decrease in annualized net sales of reformulated Opana ER*.[130]

103. During the pendency of the federal suit and its Citizen Petition, Endo became aware of additional cases of TTP or TTP-like illnesses among intravenous users of Opana ER. By March 22, 2013, Endo knew of *33* cases of confirmed or suspected TTP or TTP-like illnesses from Opana ER in intravenous users in Tennessee.[131]

104. Ultimately, the federal court rejected Endo's suit against the FDA and the FDA in turn later denied Endo's Citizen Petition and its sNDA.

105. The FDA's May 10, 2013 denial of Endo's Citizen Petition concluded that Endo had not withdrawn the original Opana ER formulation for "safety" reasons.[132] The FDA also found:

---

128 *See Endo Pharm. Inc. v. Actavis Inc.*, Civ. Action No. 12-cv-7591 (DMC)(MF), 2013 WL 4774494 (D.N.J. Sept. 3, 2013) (vacated and remanded on other grounds, 592 F. App'x 131 (3d Cir. 2014).

129 *Endo Pharm. Inc. v. Actavis Inc*., Civ. No. 12-cv-7591 (KM), 2016 WL1090356, at *3 (D.N.J. Mar. 21, 2016) (emphasis added).

130 Decl. of Julie H. McHugh, Chief Operating Officer for Endo Pharm. Inc., at ¶ 6, *Endo. Pharm. Inc. v. FDA*, Case No. 1:12-cv-01936-RBW (Dec. 18, 2012), ECF No. 28, *available at* https://www.documentcloud.org/documents/2093464-endo-v-fda-julie-mchugh-affidavit.html.

131 ENDO-OR-CID-00129895; ENDO-OR-CID-00130031.

132 ENDO-OR-CID-00000478.

> While there is an increased ability of [reformulated Opana ER] to resist crushing relative to [the original Opana ER], *data from in vitro and pharmacokinetic studies show that [reformulated Opana ER]'s extended release features can be compromised, causing the product to "dose dump," when subjected to other forms of manipulation such as cutting, grinding, or chewing, followed by swallowing*. It also appears that [reformulated Opana ER] can be prepared for insufflation (snorting) using commonly available tools and methods. *[Reformulated Opana ER] can be readily prepared for injection, despite Endo's claim that [reformulated Opana ER] tablets have "resistance to aqueous extraction (i.e. poor syringeability)." In addition, certain data suggest that [reformulated Opana ER] can more easily be prepared for injection than [the original version of Opana ER]*.[133]

106. On the same day, the FDA denied Endo's sNDA. In its decision, the FDA told Endo that there was evidence that Endo had merely replaced one form of abuse (snorting) with another, more dangerous form (intravenous use) with the reformulated Opana ER. The FDA stated in relevant part:

> [I]f the early trends in postmarketing data from the second and third reporting quarters are supported by data from further assessments, *it would appear that a reduction in abuse by insufflation [snorting] may be accompanied by a rise in intravenous abuse. This would be a transition to more dangerous behavior, as intravenous abuse is associated with a greater risk of infection, including hepatitis, HIV and bacterial pathogens, along with a greater risk for overdose and death*.[134]

107. The FDA's concern about intravenous abuse was echoed in its Citizen Petition denial, which stated in relevant part:

> If one were to treat the available data as a reliable indicator of abuse rates despite the data limitations noted above, one of the postmarketing investigations *suggests the troubling possibility that a higher (and rising) percentage of [reformulated Opana ER] abuse is occurring via injection than was the case with [the original Opana ER]*. Abuse via injection is highly dangerous, and injection of [reformulated Opana ER] in particular has been associated with a serious thrombotic thrombocytopenic purpura (TTP)-like illness.[135]

---

133 FDA Endo Citizen Pet. Denial at 5–6, ENDO-OR-CID-00000478 (emphasis added).

134 ENT000048880 (emphasis added).

135 ENDO-OR-CID-0000483 (emphasis added).

108. Despite the FDA's denial of the Opana ER sNDA and Citizen Petition, Endo remained undeterred and continued to push the argument that Opana ER was safer or less subject to abuse than generic oxymorphone. In a July 2013 Government Affairs Strategic Plan Update, Endo reiterated its intention to "[p]rovide data and supporting information to Agency officials to identify increased rates of abuse for generic oxymorphone."[136]

109. Endo knew of three additional suspected cases of individuals developing TTP or a TTP-like illness after the FDA's Citizen Petition and sNDA denials. By September 2013, Endo was aware of a total of *36* people in Tennessee who had known or suspected cases of TTP or a TTP-like illness which developed after taking Opana ER intravenously.[137]

110. Months later, Endo still persisted with its strategic objective for Opana ER to "[c]ontinue to evaluate opportunities to provide government officials with data identifying increased rates of abuse for generic oxymorphone."[138]

111. Endo continued to receive reports of TTP-like blood disorders into 2015. In May 2015, Endo had knowledge of another TTP-like case in Oklahoma in which the individual developed permanent heart, lung, and kidney damage following intravenous use of Opana ER.[139]

112. Undeterred, Endo continued the fight to get abuse deterrent labeling for Opana ER to the bitter end. In a call with investors on February 29, 2016, Endo International's Chief Executive Officer and President, Rajiv Silva, announced that the company was still seeking FDA approval for abuse deterrent labeling for Opana ER.[140] However, on June 8, 2017, the FDA took

---

136 ENDO-OPIOID_MDL-05568623.

137 ENDO-OR-CID-377373.

138 ENDO-OPIOID_MDL-06661577.

139 ENDO-OPIOID_MDL-05569284.

140 *Endo International's CEO Rajiv Silva on Q4 2015 Results – Earnings Call Transcript*, SEEKING ALPHA (Feb. 29, 2016), *available at* https://seekingalpha.com/article/3941656-endo-internationals-endp-ceo-rajiv-silva-q4-2015-results-earnings-call-transcript.

unprecedented action and requested that Endo remove the reformulated Opana ER from the market. This was the first time the FDA "ha[d] taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse," and based its decision "on a review of all available postmarketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation."[141]

113. Endo also had knowledge of other indicators of abuse or diversion of the reformulated Opana ER. While it was on the market, Endo relied heavily on continued users as a source of its reformulated Opana ER business. In internal documents, Endo stated that "[h]istorically, continuation volume has represented approximately 89% of [prescription volume]."[142]

114. Notably, even *more* of the reformulated Opana ER's business came from high doses (20 mg, 30 mg, or 40 mg). As a representative example, during the week of June 29, 2012, a whopping *75%* of Endo's Opana ER business for *reformulated* Opana ER came from high doses as shown by Endo's chart below.[143] In the same week, 60% of Endo's business for the original formulation came from high doses,[144] which was yet another red flag for Endo that its sales growth for the reformulated Opana ER was coming from abuse and diversion of its most potent doses.

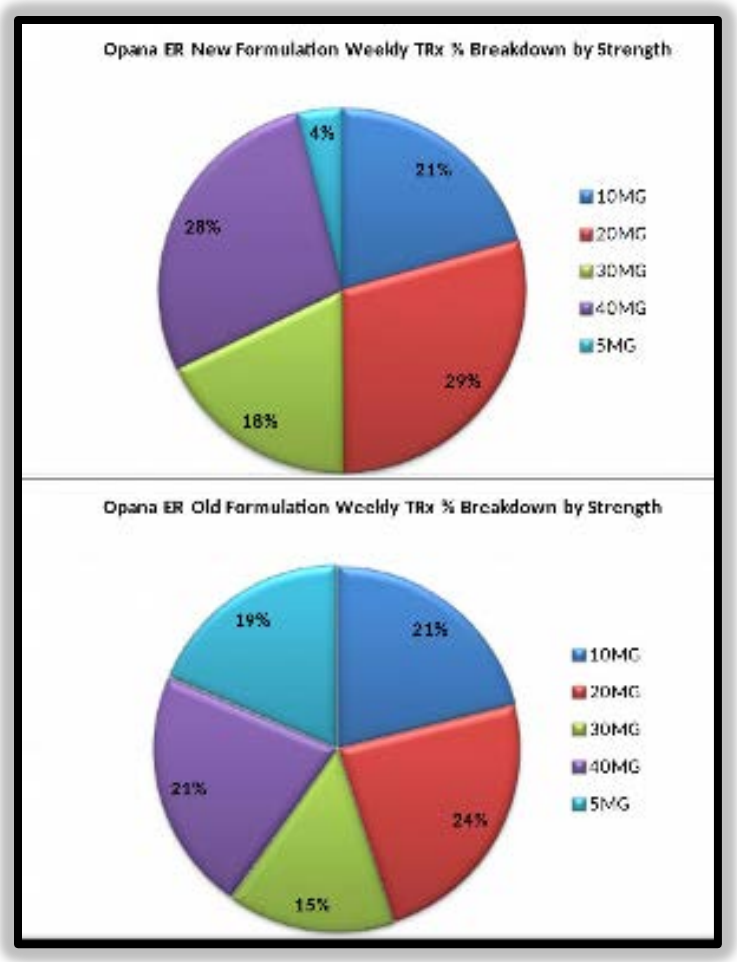
---

141 *FDA requests removal of Opana ER for risks related to abuse*, U.S. FOOD AND DRUG ADMINISTRATION, *available at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm.

142 ENDO-OR-CID-00131870.

143 ENDO-CHI_LIT-00551611 (slide 18 of 41).

144 ENDO-CHI_LIT-00551611 (slide 18 of 41).



A. DECEPTIVE SAFETY CLAIMS AND MATERIAL OMISSIONS

115. In its marketing in Tennessee, Endo deliberately misrepresented the safety and potential adverse health risks of its opioid products—including the increased risk of addiction, which it sought to minimize or failed to disclose entirely. Endo did this in numerous ways, namely by: (1) misrepresenting that Opana ER had abuse deterrent properties; (2) advancing the pseudoscience of pseudoaddiction; (3) overstating the efficacy of addiction mitigation tools; (4) representing that its opioid products produced less euphoria; (5) understating the risk of addiction; (6) failing to disclose the increased risk of addiction at higher doses of its opioid products; (7)

failing to disclose the lack of evidence concerning the effectiveness of long-term use of opioids; and (8) making sweeping, unqualified safety claims about its opioid products.

Safety Claims: Abuse Deterrence Claims

116. Opioid abuse takes several forms, the most common being oral abuse, which includes using drugs without a prescription, as well as swallowing higher or more frequent doses than prescribed. Other forms of opioid abuse include crushing, cutting, chewing, grinding, or liquefying the drug in order to snort or inject it.

117. Even before the launch of the original Opana ER, Endo knew of the high abuse and diversion potential for this narcotic. Opana ER, after all, was the more potent tablet form of Endo's Numorphan, which had been removed from the market by Endo following reports of intravenous use.[145] Moreover, Opana ER was also twice as strong as OxyContin, another Schedule II opioid.

118. Endo knew prior to launch in 2006 that:[146]

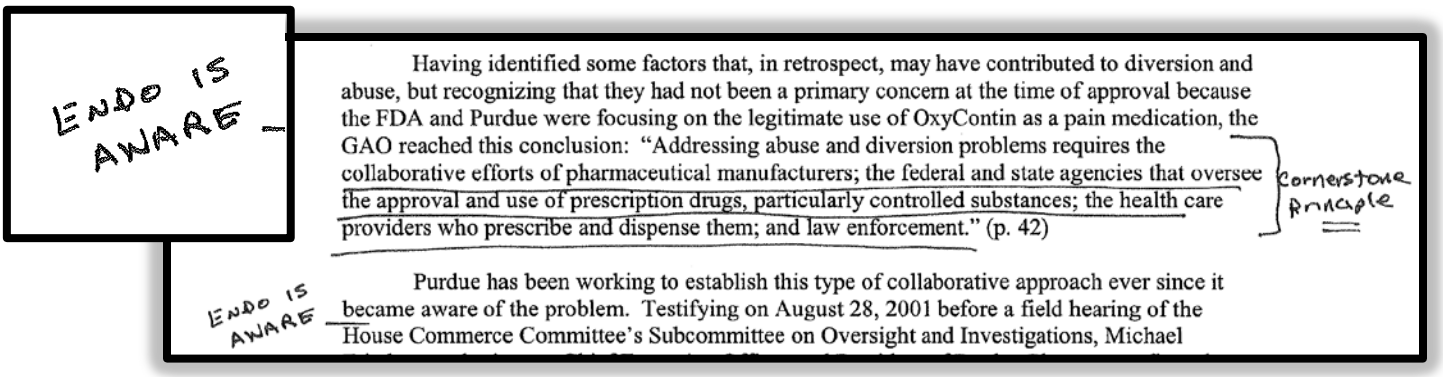
119. Endo knew of the abuse and diversion problem that would come from the launch of its extremely potent opioid, Opana ER. Handwritten notes on internal documents from Endo dated before Opana ER's launch expressly state that Endo, like Purdue, was aware of the problem of abuse and diversion.[147]

---

145 Ellen Fields, MD, MPH, *Regulatory History of Opana ER*, JOINT MEETING OF THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE AND THE ANESTHETIC AND ANALGESIC DRUG PRODUCTS ADVISORY COMMITTEE, U.S. FOOD AND DRUG ADMINISTRATION, 5 (Mar. 13–14, 2017), *available at* https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf.

146 ENDO-CHI_LIT-00543534 (highlighted emphasis in image added).

147 ENDO-CHI_LIT-00543529 (magnified inset image added).



120. In a 2007 document titled "*Better the Devil You Know* . . . Inspiring Physicians to Do the Right Thing with Opana ER," Endo's marketing consultants identified "being the stigma-free pain medication" as a marketing opportunity and recommended that Endo advance the deceptive claim that it was "a less attractive target to abusers,"[148] "less attractive to drug seekers," produced "less euphoria," and was a "responsible" choice,[149] which Endo did advance for years.

121. Endo documented that false and misleading claims about Opana ER's purported lower potential for abuse or diversion resonated with health care providers. In a 2007 internal marketing document, Endo stated that a "main message recall" for Opana ER for health care providers its sales representatives called upon was "[l]ow potential for abuse/diversion."[150]

122. Likewise, in a 2008 internal marketing document, Endo emphasized the purported "[l]ow potential for abuse/street abuse/diversion" as the primary attribute of Opana ER that was most likely to increase prescriptions.[151] In the same document, Endo stated "[l]ow abuse potential continues as the primary factor influencing physicians' anticipated increase in use of OPANA ER over the next 6 months."[152]

---

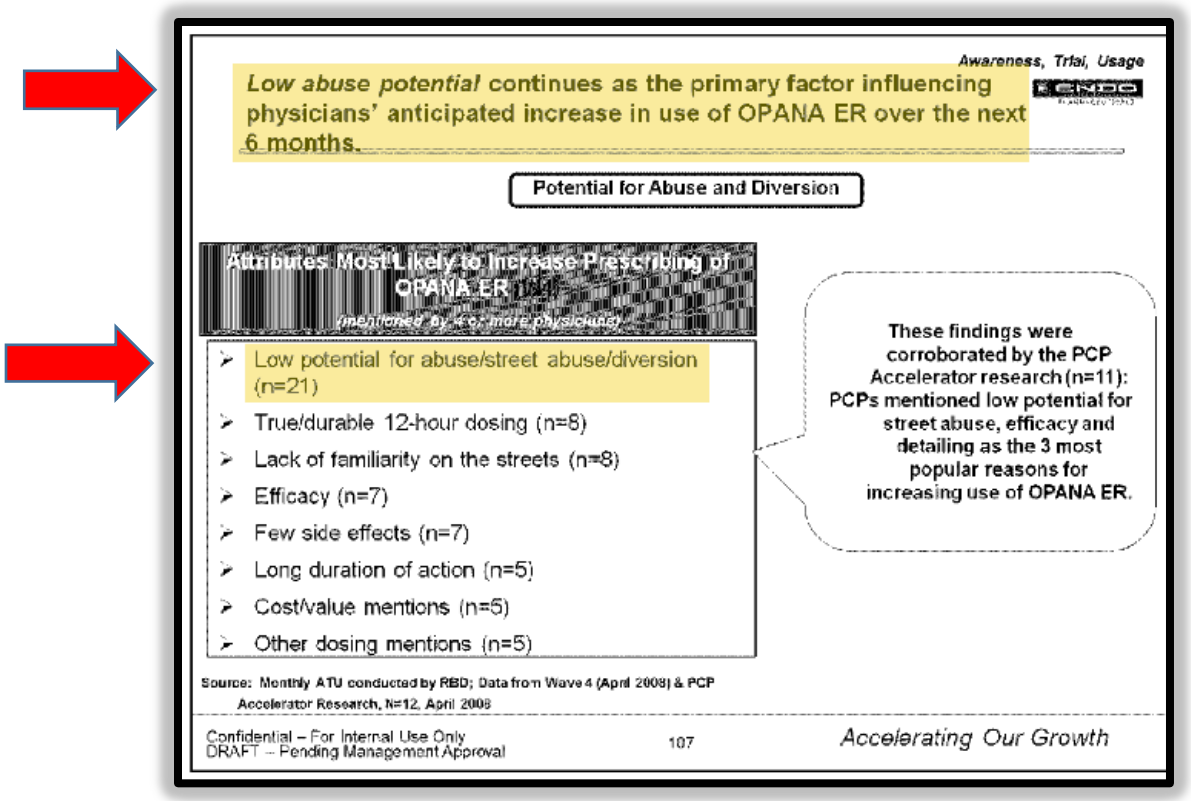
148 ENDO-OR-CID-01017684 (slides 7–9 of 120).

149 ENDO-OR-CID-00733299 (slides 1, 14, 35 of 120).

150 ENDO-CHI_LIT-00547959 (slide 18 of 136).

151 ENDO-OR-CID-00130755.

152 ENDO-OR-CID-00130755 (highlighted emphasis added in image).



123. Endo followed the recommendations of its consultants and the 2008 internal marketing document and repeatedly made low abuse potential or abuse deterrent messages to health care providers. The company's sales representatives falsely represented to health care providers that the original formulation of Opana ER was "not prone to abuse,"[153] had "low incidence of euphoria,"[154] "[l]ow abuse potential,"[155] "[l]ow abuse potential and low euphoria

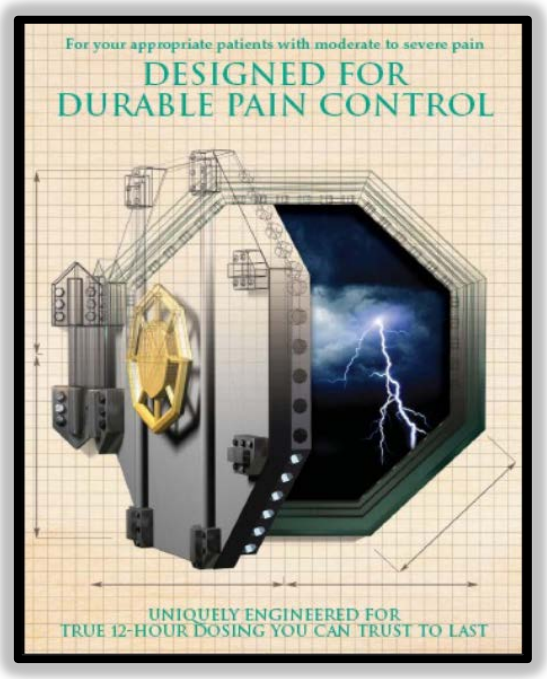
[153] ENDO-CHI_LIT-00548031.

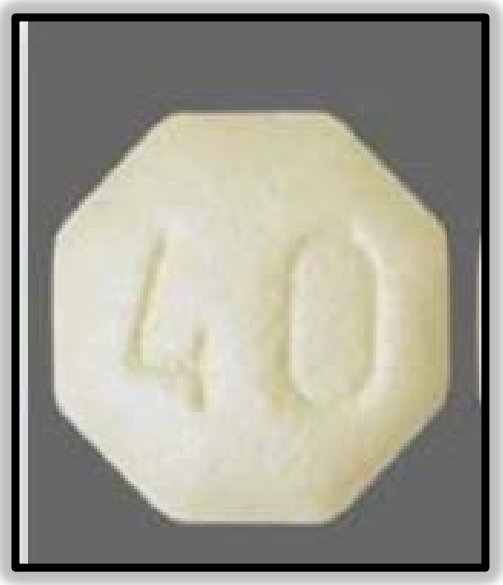
[154] ENDO-CHI_LIT-00548031, -045

[155] ENDO-CHI_LIT-00548034, -041.

potential,"[156] was "very hard to adulterate into making it an immediate release drug,"[157] was "very resistant to adulteration"[158] or made other similar statements.[159]

124. Endo advanced the false abuse deterrent and lower abuse potential claims in other ways. For example, the company also featured the image of an octagon-shaped vault with the tagline "Designed for Durable Pain Control" to promote the original formulation of Opana ER.[160] The octagonal vault corresponded to the shape of the Opana ER pill at the time and reinforced the deceptive message that Opana ER was safer, less attractive to abusers, and harder to abuse.





156 ENDO-CHI_LIT-00548117.

157 ENDO-CHI_LIT-00547958; -8033.

158 ENDO-CHI_LIT-00548046.

159 ENDO-CHI_LIT-00548031, -041, -045, -115 ("Low incidence of abuse due to low incidence of euphoria."), -117 ("less risk of narcotic related problematic [sic]"), -135 ("decreased potential for abuse"), -136 ("low abuse potential"), -146 ("Safety of immediate release Opana and pain control for breakthrough pain in almost all patients without significant abuse."), -198 ("[g]enerally has low abuse potential").

160 ENDO-CHI_LIT-00538937.

125. Endo trained its sales representatives to use the "vault" or "safe" image, shown above, in sales calls.[161] Endo knew that the "vault concept had great 'stopping power'" with physicians and was more likely to hold their attention.[162] While the company claimed the vault concept referred to "durability," the image served as an abuse deterrent claim that it could not make expressly without FDA scrutiny.

126. In its marketing in Tennessee, Endo also falsely represented that the reformulated Opana ER was an abuse deterrent, had abuse deterrent properties, was crush resistant, remained intact, or was otherwise resistant to abuse.[163]

127. Endo's deceptive messaging was especially critical to the reformulated Opana ER's success, which hinged on clearly distinguishing the two formulations. Otherwise, health care providers, health insurance companies, and managed care companies would prioritize cheaper generic versions of the original formulation and Endo would lose money.

128. Because Endo was concerned with losing business, the company continued to market the reformulated version of its most commercially successful opioid product, Opana ER, as an abuse deterrent or less capable of abuse well after it knew that this was not true.

129. Endo knew that the reformulated Opana ER showed no clinically-significant benefit over the old formulation concerning abuse,[164] could easily be cut or chewed, and did not stay intact.[165]

---

161 END00000122.

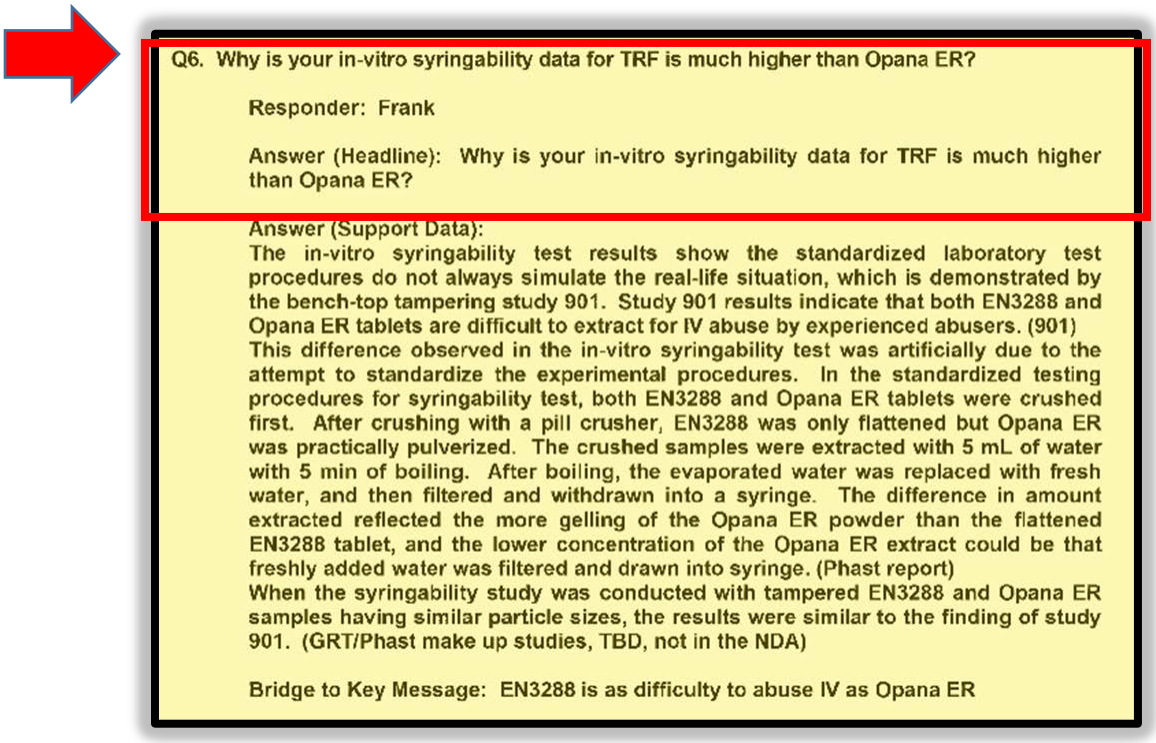
162 END00000122.

163 ENDO-CHI_LIT-00548031; ENDO-CHI_LIT-00548031, -045; ENDO-CHI_LIT-00548034, -041; ENDO-CHI_LIT-00548117; ENDO-CHI_LIT-00547958; -8033; ENDO-CHI_LIT-00548046; ENDO-CHI_LIT-00548031; -041, -045; -115; -117; -135; -136; -146; -198; ENDO-OR-CID-00770083; ENDO-OR-CID-00421982; ENDO-OR-CID-00492371; *see also*, ENDO-OR-CID-00240875.

164 ENDO-OR-CID-00351932 (emphasis added).

165 www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (pp. 3–4) (emphasis added); *see also*, ENDO-OR-CID-00073848 (n. 5); ENDO-OR-CID-00023768.

130. Endo's abuse deterrence marketing was especially egregious given that Endo's own studies had predicted intravenous abuse *from the beginning*. As early as August 30, 2010, while the reformulated Opana ER was being considered by the FDA and well before it was marketed, Endo's own *in vitro* studies showed the reformulated Opana ER had "much higher" "syringeability" than the old formulation. In fact, Endo anticipated this question from an FDA Advisory Committee and carefully crafted a response (shown below) that, at best, asserted that the reformulated Opana ER (referred to below as "TRF" and "EN3288") had the same capacity for intravenous abuse as the old formulation of Opana ER (referred to below as "Opana ER").[166]



Q6. Why is your in-vitro syringability data for TRF is much higher than Opana ER?

Responder: Frank

Answer (Headline): Why is your in-vitro syringability data for TRF is much higher than Opana ER?

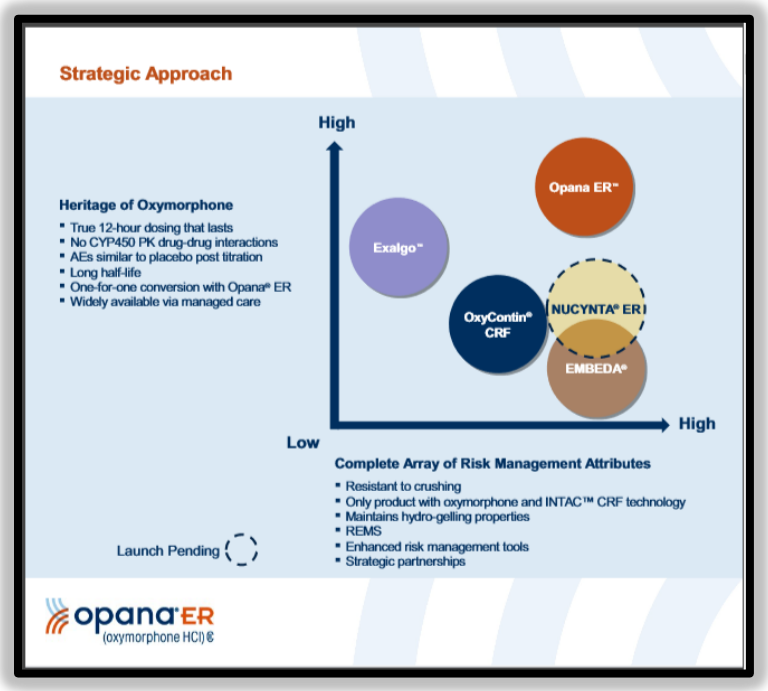
Answer (Support Data):
The in-vitro syringability test results show the standardized laboratory test procedures do not always simulate the real-life situation, which is demonstrated by the bench-top tampering study 901. Study 901 results indicate that both EN3288 and Opana ER tablets are difficult to extract for IV abuse by experienced abusers. (901)
This difference observed in the in-vitro syringability test was artificially due to the attempt to standardize the experimental procedures. In the standardized testing procedures for syringability test, both EN3288 and Opana ER tablets were crushed first. After crushing with a pill crusher, EN3288 was only flattened but Opana ER was practically pulverized. The crushed samples were extracted with 5 mL of water with 5 min of boiling. After boiling, the evaporated water was replaced with fresh water, and then filtered and withdrawn into a syringe. The difference in amount extracted reflected the more gelling of the Opana ER powder than the flattened EN3288 tablet, and the lower concentration of the Opana ER extract could be that freshly added water was filtered and drawn into syringe. (Phast report)
When the syringability study was conducted with tampered EN3288 and Opana ER samples having similar particle sizes, the results were similar to the finding of study 901. (GRT/Phast make up studies, TBD, not in the NDA)

Bridge to Key Message: EN3288 is as difficulty to abuse IV as Opana ER

[166] ENT000023417 (highlighted emphasis added in image); ENDO-OR-CID-00082828; ENDO-OR-CID-00010938; *see also*, ENDO-OR-CID-00019657.

131. Despite this knowledge, Endo's strategy from the beginning was to position its reformulated Opana ER as having superior abuse deterrence to competing products.[167] For example, a 2011 Endo document titled Opana™ ER Playbook" described the franchise vision for Opana ER to "become the branded oral-solid [Long-Acting Opioid] of choice *based on the most complete array of tamper-resistant properties and attributes* combined with the heritage of oxymorphone.[168]

132. Endo advanced this misleading marketing strategy in 2010[169] and 2011, as shown by the slide below.[170]



167 *See, e.g.*, ENDO-OR-CID-00453174 (stating "[reformulated Opana ER] will become the tamper resistant solution of choice based on having the most complete array of tamper resistant properties and the heritage of oxymorphone.").

168 ENDO-OR-CID-00633679 (slide 4 of 54) (emphasis added).

169 ENDO-OR-CID-00465134 (slide 10 of 16).

170 ENDO-OR-CID-00633679 (slide 5 of 54).

133. On December 9, 2011, the FDA denied Endo's request to include any reference to crush resistance or abuse deterrence. The FDA told Endo:

> While the new formulation has demonstrated a minimal improvement in resistance to tampering by crushing, thereby limiting the likelihood of abuse by crushing followed by ingestion, and by insufflation (snorting) to some degree, *it can still be…cut…rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation*; although whether … tablets can be snorted was not studied. *Of more concern, when chewed … the new formulation essentially dose dumps like an immediate-release formulation.*[171]

134. Endo continued to make abuse deterrence claims including through a marketing effort that rebranded Opana ER as "Opana ER with INTAC technology" and claims that Opana ER was "originally designed to be crush resistant."[172] Notably, this marketing occurred even *after* the FDA had denied Endo's request to add abuse deterrence labeling and told Endo that these claims were deceptive.

135. Endo was especially focused on "abuse deterrence" advocacy and messaging in Tennessee[173] and marketed Opana ER as less abuseable despite knowing that the ease of its intravenous abuse through cutting specifically led to viral outbreaks of HIV, Hepatitis C, and TTP in Kingsport, Tennessee and elsewhere.

136. Endo's marketing executives wanted to add a suffix to the name of the reformulated Opana ER that would imply abuse deterrence to differentiate it from its generic competitors. In an internal e-mail on February 8, 2010, Endo's Vice President of Regulatory Affairs tried to brush back efforts from the top marketing executive for the Opana brand with the following e-mail:

> The modifier that I believe will be accepted is ER.

---

171 www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (emphasis added); *see also*, ENDO-OR-CID-00073848 (citing this language from Dec. 9, 2011 decision).

172 ENDO-OR-CID-00421982; ENDO-OR-CID-00492371; *see also*, ENDO-OR-CID-00240875.

173 ENDO-OR-CID-00223057.

> Any other modifier that is descriptive of the technology provides little, if any, useful information to the prescriber *because we don't have data to demonstrate that the technology conveys any benefit to the patient*.
>
> If FDA eventually describes the characteristics and minimum requirements of a tamper resistant or abuse deterrent formulation they may establish an appropriate suffix at that time.[174]

137. But Endo's marketing team won out. In February 2012, after initially deciding against it,[175] Endo began marketing and selling the reformulated Opana ER under the rebranded name "Opana ER with INTAC Technology" anyway even though the FDA never approved abuse deterrence labeling for the reformulated Opana ER.

138. Endo used "with INTAC Technology" as its most prominent abuse deterrent message by making it part of the brand name for the reformulated Opana ER. Endo employed the phrase "with INTAC Technology" whenever it mentioned the brand name—something Endo did repeatedly within the same marketing document to drive this false claim home.

139. Two months later, in April 2012, Endo received a response letter from the FDA directly stating that Endo's claims about Opana ER's INTAC technology were misleading, despite an included disclaimer. The FDA wrote:

> The proposed detail aid contains numerous claims and presentations describing Opana ER's new formulation and its INTAC™ technology. . . . The totality of these claims and presentations suggest that, as a result of its new formulation Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. *In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC™ technology" confers some form of abuse deterrence properties when this has not been demonstrated by substantial evidence*. Although we acknowledge that there is evidence to support some limited improvement in mechanical stability and strength attributable to the new technology as well as a minimal improvement in resistance to tampering in efforts to abuse Opana ER intranasally, *there are several limitations to this data*. . . . We acknowledge that the proposed detail aid presents statements such as, "The clinical

[174] ENDO-OR-CID-00448291 (emphasis added).

[175] ENDO-OR-CID-00179312.

> significance of INTAC technology or its impact on abuse/misuse has not been established for the new formulation of Opana ER' on various pages of the piece; *however, these and similar statements do not mitigate the overwhelming misleading impression*. Therefore, [the FDA's Division of Professional Drug Promotion] recommends that these claims and presentations regarding Opana ER's new formulation be deleted from the proposed detail aid. *We are especially concerned from a public health perspective because the presence of this information in the detail aid could result in health care practitioners or patients thinking that the new formulation is safer than the old formulation, when this is not the case*.[176]

140. Despite being told by the FDA that reformulated Opana ER did not stay intact, that when chewed it "essentially dose dumps like an immediate-release formulation," and that Endo's "INTAC" technology claims misleadingly imply abuse deterrence, *Endo plowed ahead and made these (and other) abuse deterrence claims anyway*.

141. Endo conducted a crude cost/benefit analysis,[177] decided that there was more financial upside to making the claims than downside, and dismissed out-of-hand the FDA's expressed public health concern. Again, Endo knew that unless it was able to distinguish its reformulated Opana ER to health care providers,[178] managed care companies, insurance providers, and consumers generally, there would be no reason to prescribe a reformulated Opana ER over generic versions of the old formulation, which were substantially cheaper.

142. Following the FDA's April 30, 2012 letter about Endo's use of Opana ER with INTAC Technology, on May 15, 2012, William Best, Endo's Director of Promotional Regulatory Affairs, sent an e-mail to Bob Barto, Endo's Vice President of Regulatory Affairs stating:

> Bob,

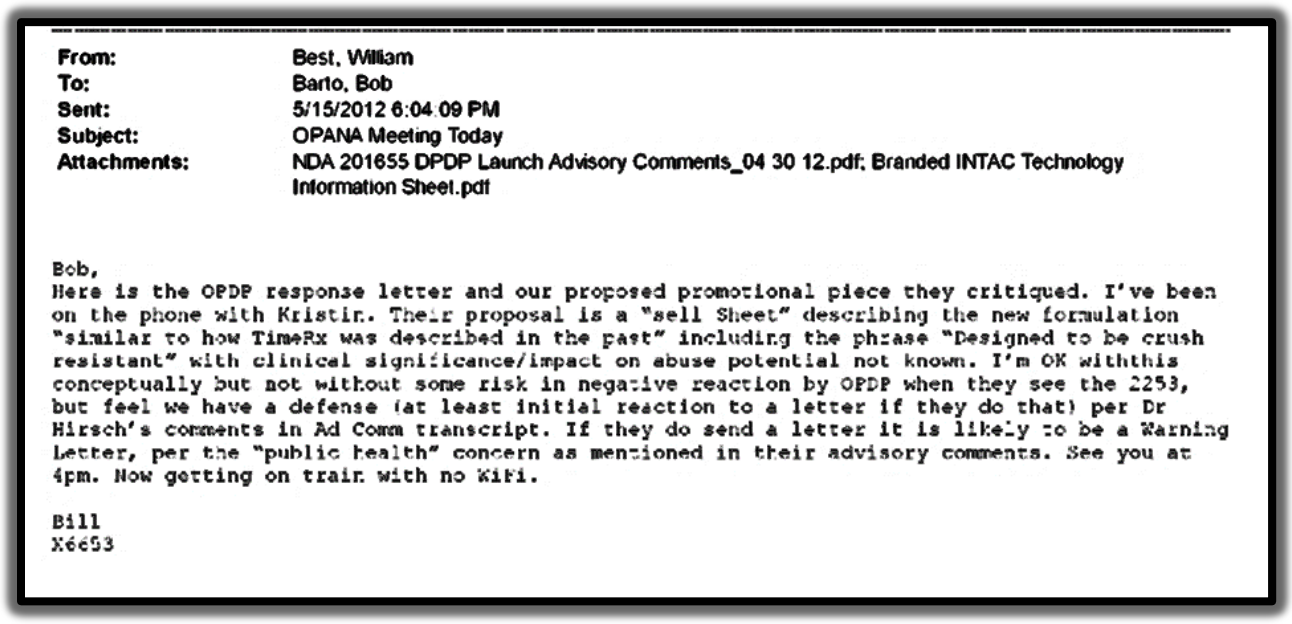
---

176 ENDO-OR-CID-00009163, -164 (emphasis added).

177 ENT000040654 (emphasis added).

178 *See, e.g.*, ENDO-OR-CID-01307517 (stating "Intac … [m]any customers have expected to hear something close to the full explanation we can finally provide them with about our new formulation, as one of her customers indicated to her. However, even if it's no surprise to them, do make a point of providing this information. They need to know our intent in coming out with the new formulation; <u>just be sure to provide **ALL** elements of the message including the reminder of the boxed warning that's consistent with all preparations in the class</u>." (Emphasis in original)).

> Here is the [FDA] OPDP[179] response letter and our proposed promotional piece they critiqued. I've been on the phone with [consultant]. Their proposal is a "sell Sheet" describing the new formulation "similar to how TimeRx was described in the past" including the phrase "Designed to be crush resistant" with clinical significance/impact on abuse not known. *I'm OK withthis* [sic] *conceptually but not without some risk in negative reaction by OPDP when they see the 2253,*[180] but feel we have a defense (at least initial reaction to a letter if they do that) per Dr. Hirsch's comments in Ad Comm transcript. *If they do send a letter it is likely to be a Warning Letter, per the "public health" concern as mentioned in their advisory comments*. See you at 4pm. Now getting on train with no WiFi.
>
> Bill[181]



From: Best, William
To: Barto, Bob
Sent: 5/15/2012 6:04:09 PM
Subject: OPANA Meeting Today
Attachments: NDA 201655 DPDP Launch Advisory Comments_04 30 12.pdf; Branded INTAC Technology Information Sheet.pdf

Bob,
Here is the OPDP response letter and our proposed promotional piece they critiqued. I've been on the phone with Kristin. Their proposal is a "sell Sheet" describing the new formulation "similar to how TimeRx was described in the past" including the phrase "Designed to be crush resistant" with clinical significance/impact on abuse potential not known. I'm OK withthis conceptually but not without some risk in negative reaction by OPDP when they see the 2253, but feel we have a defense (at least initial reaction to a letter if they do that) per Dr Hirsch's comments in Ad Comm transcript. If they do send a letter it is likely to be a Warning Letter, per the "public health" concern as mentioned in their advisory comments. See you at 4pm. Now getting on train with no WiFi.

Bill
X6653

143. Endo moved quickly and began its "INTAC" messaging nationwide two days later on May 17, 2012.[182] Endo rolled out the misleading abuse deterrent message (that FDA had

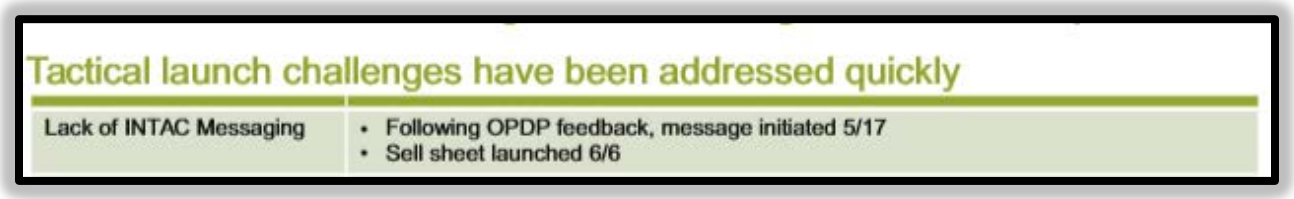
[179] OPDP refers to the FDA's Office of Prescription Drug Promotion.

[180] "2253" is a reference to the FDA's form 2253 which is submitted to FDA *after* the advertisement has already been made available to the public.

[181] ENT000040654 (emphasis added).

[182] ENDO-OR-CID-00380237 (slide 5 of 155).

already told Endo was misleading) to ensure its wide dissemination across the country, including in Tennessee.[183]



144. In a June 21, 2012 "Opana® ER Action Plan," Endo stated its intent to "[a]ccelerate field distribution of INTAC Sell Sheet," which it described as a "key resource," to its sales representatives, including those in Tennessee.[184] Endo stated in the same "Opana® ER Action Plan" its intention to "[p]osition Endo to targeted HCP groups as the responsible and supportive industry partner within the pain management space" and to "[b]uild out story of OPANA ER evolution focusing on the proactive move to new formulation designed to be crush resistant."[185]

145. During the third week of June 2012, Endo trained all its Opana ER sales representatives, including those in Tennessee, to advance the claim that the reformulated Opana ER was "designed to be crush-resistant" and "the INTAC Technology is included in the new formulation for that purpose" in sales calls with providers.[186]

146. Endo made false abuse deterrent claims in sales calls as a way to blunt news stories about increasing abuse and diversion of Opana ER.

147. For example, on July 11, 2012, USA TODAY published a story titled "Opana Abuse in USA Overtakes OxyContin," which as the headline indicates, described the rise of Opana ER

---

183 ENDO-OR-CID-00117276 (documenting INTAC claim with Tennessee doctor by April 26, 2012).

184 ENDO-OR-CID-01311385 (document states draft, but no more recent version of the document is known to have been produced).

185 ENDO-OR-CID-01311392.

186 ENDO-OR-CID-00770083.

abuse following OxyContin's reformulation.[187] The story revealed that hot spots for OxyContin abuse had become hot spots for Opana ER abuse.

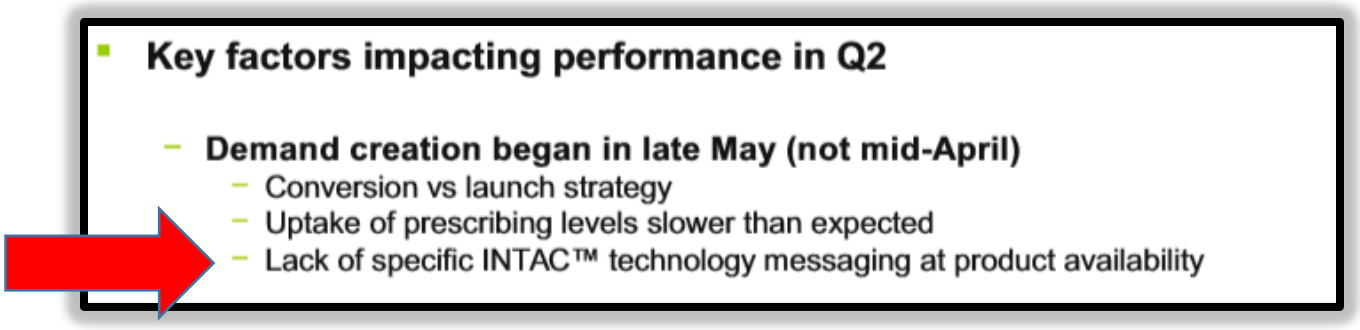
148. That same day, Endo's marketing department instructed *all* its sales representatives nationwide to respond to health care providers' questions about the USA TODAY Opana ER story with, among other things, the following:

> Endo discontinued the manufacturing of the original formulation of Opana ER in early 2012 and *now only manufactures the new formulation of Opana ER with INTAC™ technology which is designed to be crush-resistant*.[188]

149. Endo also directed its promotional speakers, who were usually doctors, to make similar comments in response to questions about the USA TODAY story, including:

> Endo discontinued the manufacturing of the original formulation of Opana ER in early 2012 *and now only manufactures the new formulation of Opana ER with INTAC technology which is designed to be crush resistant*. However, there is no evidence that the reformulation is less subject to misuse, abuse, diversion, overdose, or addiction.[189]

150. Consistent with its original pre-launch strategy, Endo had wanted to go even further than the misleading claims it was already making. In a Quarterly Business Review for Opana ER dated July 24, 2012, Endo cited the "[l]ack of specific INTAC™ technology messaging at product availability" as a "key factor" that impacted sales performance.[190]



187 ENDO-OR-CID-00839051.

188 ENDO-OR-CID-00009156 (emphasis added).

189 ENDO-OR-CID-00430776 (emphasis added).

190 ENDO-CHI_LIT-00551611 (slide 2 of 41).

151. Endo knew that without aggressive abuse deterrence messaging, its flagship drug would fail.

152. Endo continued to promote the abuse deterrence claims even after having actual knowledge of significant abuse soon after the launch of reformulated Opana ER, which was foretold in Endo's own data and the FDA's initial sNDA decision in December 2011.[191]

153. In Tennessee, Endo continued to make abuse deterrent claims in its marketing after it became aware of the spike in abuse of the reformulated Opana ER from cutting or chewing followed by intravenous injection.[192]

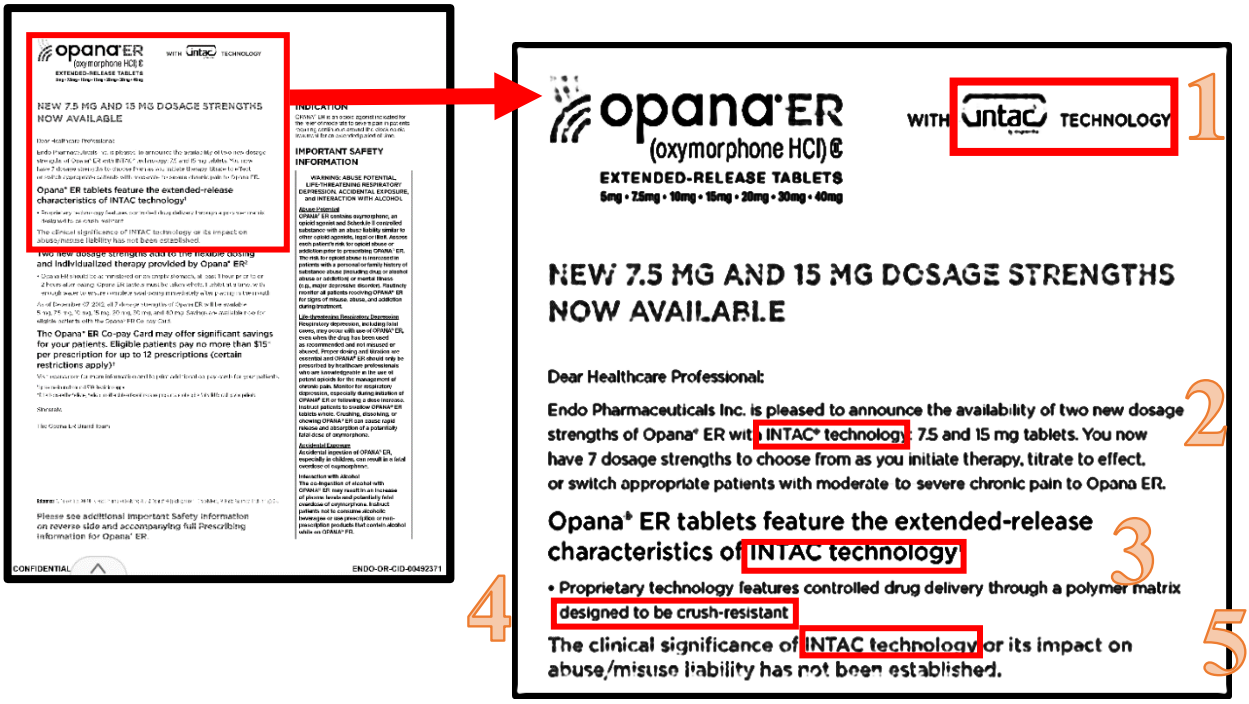
154. Endo also continued to push false abuse deterrence claims in its marketing materials in Tennessee despite knowledge of the TTP cluster and high Opana ER abuse rates in Tennessee. In December 2012, with full knowledge of the TTP cluster, Endo sent a "Dear Doctor" letter to providers nationwide, including in Tennessee, that contained at least five prominent abuse deterrent or related claims.[193]

---

[191] www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf (pp. 3–4) (emphasis added); *see also*, ENDO-OR-CID-00073848 (n. 5); ENDO-OR-CID-00000482; -483; ENT000023417; ENDO-OR-CID-00082828; ENDO-OR-CID-00010938.

[192] ENDO-OR-CID-00421982; ENDO-OR-CID-00492371; *see also*, ENDO-OR-CID-00240875 (e-mail to Field Sales Team discussing 50 copies of letter identified as OP-02555).

[193] ENDO-OR-CID-00421982; ENDO-OR-CID-00492371; *see also*, ENDO-OR-CID-00240875 (e-mail to Field Sales Team discussing 50 copies of letter identified as OP-02555).



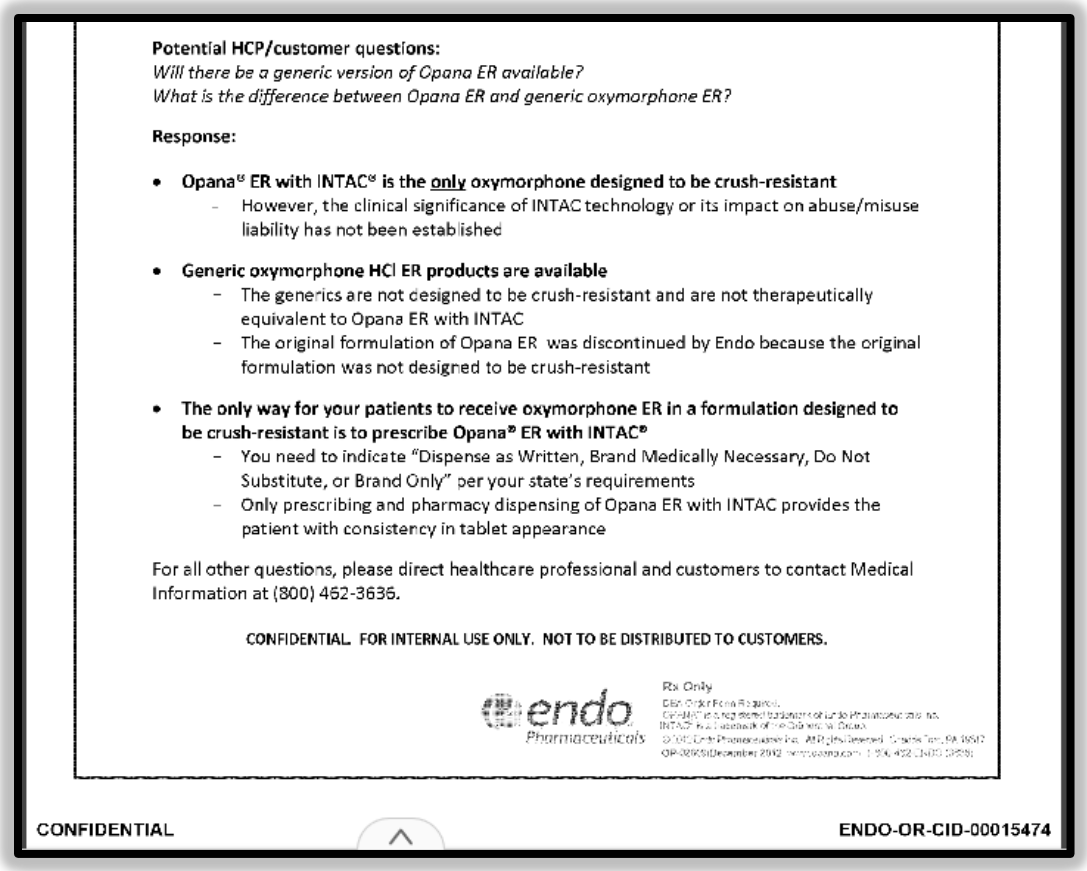
155. At the same time, Endo's sales representatives, including those in Tennessee, each received 50 copies in the initial roll-out of this Dear Doctor letter known internally as OP-02555. Endo instructed its sales representatives regarding this letter as follows:

> Your role during the immediate future will **not** change as you will continue to focus 100% of your efforts on promoting Opana ER with INTAC technology for appropriate patients who suffer from moderate-to-severe chronic pain. …. Additional quantities are available for order from SirSpeedy's EZ-Order: Opana® ER w/INTAC® technology (7.5 and 15 mg tablet resources):
>
> OP-02555 - Dear HCP 7.5 & 15 mg Letter (1 Pack of 50 shrink-wrapped with 50 PIs) This is a promotional as well as a leave behind resource. This resource will also be available as a rep triggered letter on December 10[.][194]

156. Endo's deception persisted. In an internal memorandum dated January 2013, Endo's Opana ER Brand and Sales Training Team sent the following to "all customer facing roles," including Endo's sales representatives:

---

194 ENDO-OR-CID-00240875 (emphasis in original).



Potential HCP/customer questions:
Will there be a generic version of Opana ER available?
What is the difference between Opana ER and generic oxymorphone ER?

Response:

- **Opana® ER with INTAC® is the only oxymorphone designed to be crush-resistant**
  - However, the clinical significance of INTAC technology or its impact on abuse/misuse liability has not been established
- **Generic oxymorphone HCl ER products are available**
  - The generics are not designed to be crush-resistant and are not therapeutically equivalent to Opana ER with INTAC
  - The original formulation of Opana ER was discontinued by Endo because the original formulation was not designed to be crush-resistant
- **The only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe Opana® ER with INTAC®**
  - You need to indicate "Dispense as Written, Brand Medically Necessary, Do Not Substitute, or Brand Only" per your state's requirements
  - Only prescribing and pharmacy dispensing of Opana ER with INTAC provides the patient with consistency in tablet appearance

For all other questions, please direct healthcare professional and customers to contact Medical Information at (800) 462-3636.

CONFIDENTIAL. FOR INTERNAL USE ONLY. NOT TO BE DISTRIBUTED TO CUSTOMERS.

endo Pharmaceuticals

Rx Only

CONFIDENTIAL **ENDO-OR-CID-00015474**

157. Endo instructed its sales representatives to provide health care providers with messages that were deceptive for multiple reasons. First, the brand name "Opana ER with INTAC" is an abuse deterrence claim that the Opana ER pill remains intact at all times, when this is not true. Second, the phrase "designed to be crush-resistant" misleads or tends to mislead consumers that reformulated Opana ER is more resistant to abuse or manipulation than it actually is. Third, as the FDA warned Endo, including a disclaimer that "the clinical significance of INTAC technology or its impact on abuse/misuse liability has not been established" does not mitigate the overall deception of the ad or the express deceptive claims made. Fourth, Endo's memorandum claims that reformulated Opana ER is superior to generic Opana ER under the old formulation when Endo's own data showed that reformulated Opana ER was as bad as or worse than the old

formulation for common forms of abuse. Fifth, Endo did not discontinue the original formulation because it was susceptible to abuse or for safety reasons, it did so for monetary reasons.

158. At the same time, Endo also instructed its sales representatives to distinguish reformulated Opana ER from competing generics by giving providers a new sales message: "The only way for your patients to receive oxymorphone ER in a formulation designed to be crush-resistant is to prescribe Opana® ER with INTAC®."[195]

159. Endo made these claims despite actual knowledge of significant reports of abuse from the reformulated Opana ER. In January 2013, Endo knew:

- that the CDC and Tennessee Department of Health would release its epidemiology report on the TTP cluster in eastern Tennessee, which prompted Endo to prepare a draft internal report titled "OPANA ER TTP APPALACHIA ABUSE CASES–NEXT STEPS,"[196] and

- of 14 instances in Tennessee in which individuals contracted TTP following injection drug use from injecting reformulated Opana ER[197] and of additional cases of TTP or a TTP-like disease beyond those referenced in the Tennessee Department of Health and CDC's report.

160. Three months later, Endo was still making abuse deterrence claims despite knowledge of at least 33 confirmed, suspected, or related cases of TTP or TTP-like diseases predominantly in Tennessee, including 3 in Chattanooga.[198]

161. Endo also made its abuse deterrence claims despite actual knowledge that there was no way to prevent intravenous injection *in the first place* because oxymorphone easily dissolves in water. In its public relations preparation, Endo's Vice President of Pharmacovigilance and Risk

---

195 ENDO-CHI_LIT-00556179 (slide 10 of 104).

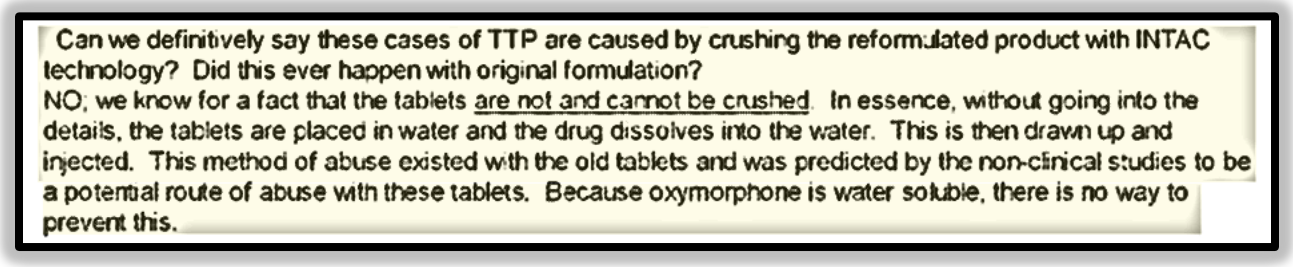
196 ENDO-OR-CID-00975644.

197 ENDO-OR-CID-00125419; ENT000044806; ENT000045113.

198 ENDO-OR-CID-00129895; ENDO-OR-CID-00130031.

Management & Senior Clinical Advisor responded to internal questions and admitted to the intravenous injection form of abuse:

> [Intravenous] abuse existed with the old tablets and was predicted by the non-clinical studies to be a potential route of abuse *with these tablets*. ***Because oxymorphone is water soluble, there is no way to prevent this***.[199]


Can we definitively say these cases of TTP are caused by crushing the reformulated product with INTAC technology? Did this ever happen with original formulation?
NO; we know for a fact that the tablets are not and cannot be crushed. In essence, without going into the details, the tablets are placed in water and the drug dissolves into the water. This is then drawn up and injected. This method of abuse existed with the old tablets and was predicted by the non-clinical studies to be a potential route of abuse with these tablets. Because oxymorphone is water soluble, there is no way to prevent this.

162. Endo only temporarily stopped using "Opana ER with INTAC" as the brand name for its reformulated Opana ER in May 2013—following the FDA's denial of Endo's Citizen Petition.[200] After the denial, Endo stated its intention to suspend use of the "INTAC: designed to be [crush]-resistant" message, but this did not last.

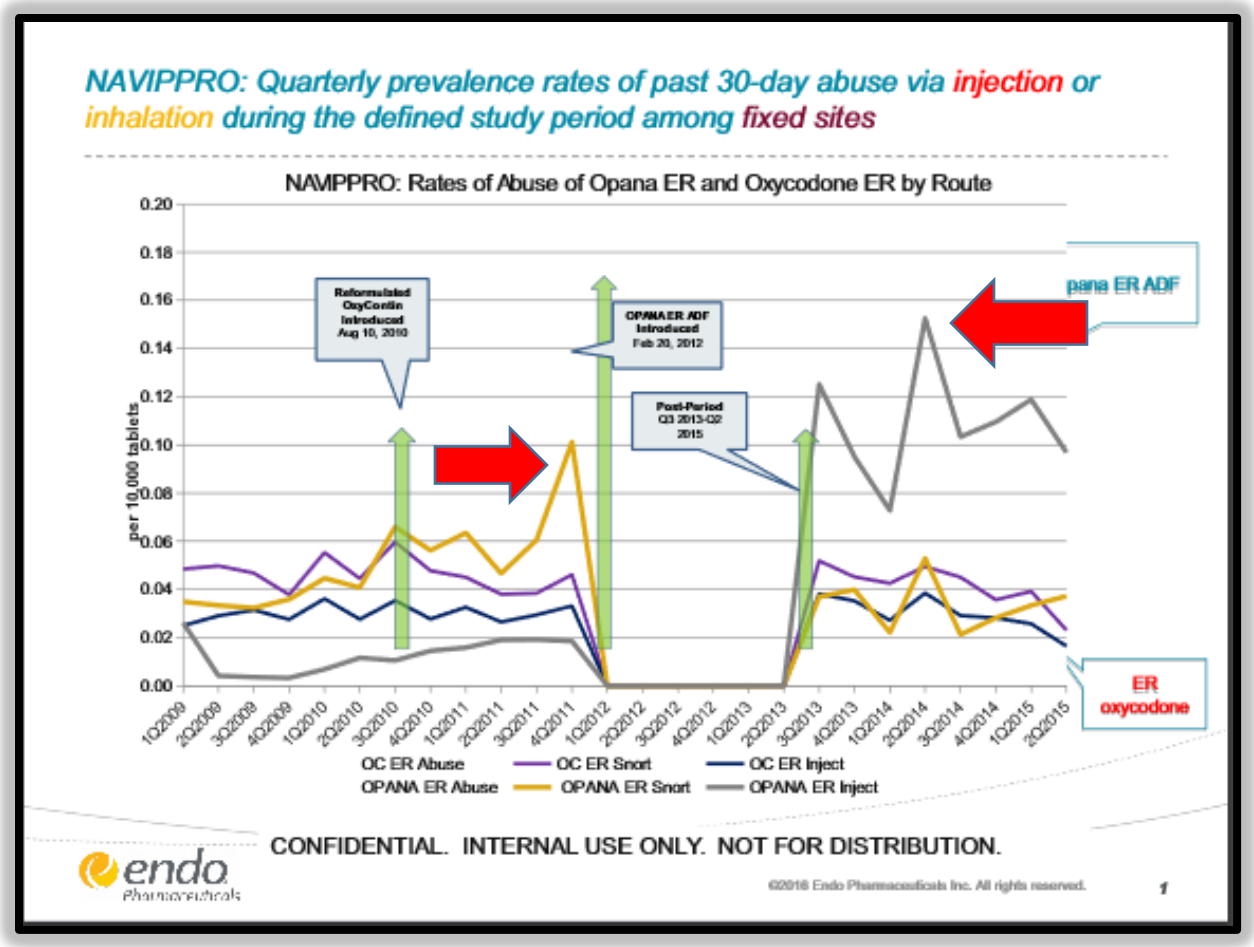
163. As illustrated by a chart from 2009-2015 that omitted data from 2012 to 2013, *Endo knew that there were higher rates of intravenous abuse of the reformulated Opana ER than rates of snorting abuse of the old formulation of Opana ER*.[201] Endo had replaced snorting with higher rates of abuse through intravenous injection, which was even more dangerous.

---

199 ENDO-OR-CID-00848440 (highlighted, bold, and italicized emphasis added) (The next question and response reads: "[I]s it accurate to say our reformulated product is successfully demonstrating the crush-resistant properties for which it was designed? YES; the tablets cannot be crushed.").

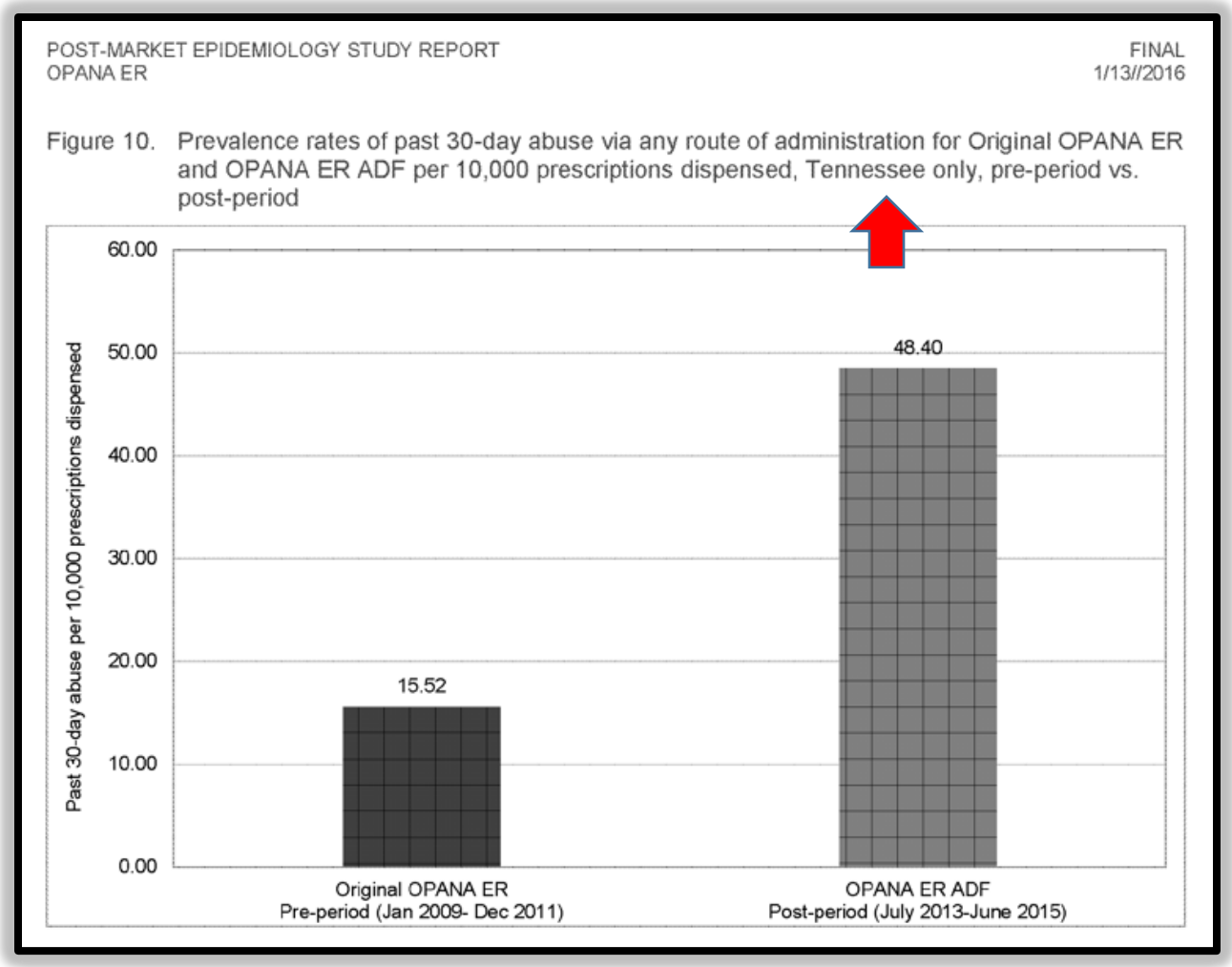
200 ENDO-OR-CID-00939196 (slide 3 of 8); ENDO-OR-CID-00157568; *see* ENDO-OR-CID-000002651 (showing a September 2015 date).

201 ENDO-OPIOID_MDL-4940040 (red arrows added to Endo-created chart).



164. Moreover, Endo knew based on reports it commissioned that the reformulated Opana ER was not abuse deterrent, but instead had *over three times* the prevalence rate for abuse in Tennessee than the original Opana ER. For example, Endo commissioned and reviewed a NAVIPPRO report dated January 13, 2016 that featured the following graphic:[202]

[202] ENDO-OPIOID_MDL-04950334.



165. Endo's abuse deterrent claims continued even after Endo had knowledge of other serious diseases being spread through intravenous use of Opana ER. On April 24, 2015, as Endo knew at the time, the CDC first published a report that connected a significant outbreak of HIV in Scott County, Indiana, which "involves a rural population, historically at low risk for HIV, in which HIV infection spread rapidly within a large network of persons who injected prescription opioids."[203] Endo knew that Opana ER was the main prescription opioid at issue from the CDC

[203] Caitlin Conrad, et al., *Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone – Indiana, 2015, Morbidity and Mortality Weekly Report (MMWR)*, CENTERS FOR DISEASE CONTROL AND PREVENTION, 64(16):443-444 (May 1, 2015), *available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm.

report and that the outbreak was very serious. USA TODAY published an article shortly after the release of the report that referenced Opana and quoted the CDC Director as saying that Scott County, Indiana had a higher incidence of HIV than "*any country in sub-Saharan Africa*" and "*more people infected with HIV through injection drug use than in all of New York City last year*."[204]

166. On May 1, 2015, the CDC published a *separate* report that found a *364% increase in new Hepatitis C cases* in Tennessee, Kentucky, Virginia, and West Virginia in individuals who used drugs intravenously.[205]

167. One week later, Endo employees sent internal e-mails circulating an article from Bloomberg News about the second CDC report, titled "Abuse of Pain Pills Fuels Virus's Spread, Confounding Regulators," in which the CDC's lead author is quoted as blaming the surge of cases on Opana.[206] Endo was aware of the CDC report by May 2015 and submitted a response to the Bloomberg News.[207]

168. Endo continued to use the brand name "Opana ER with INTAC" in September 2015 when it returned to instructing its sales representatives in a "Sales Training Implementation Guide" that the name of the drug was "Opana® Extended release CII with INTAC® technology" and

---

[204] Laura Ungar, *Indiana Community's HIV Outbreak a Warning to Rural America*, USA TODAY (May 17, 2015), *available at* https://www.usatoday.com/story/news/nation/2015/05/13/indiana-hiv-outbreak-a-warning-to-rural-america/27182089/ (emphasis added).

[205] *Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged <30 Years – Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012*, MORTALITY AND MORBIDITY WEEKLY REPORT, CENTERS FOR DISEASE CONTROL AND PREVENTION (May 7, 2015), *available at* https://content.govdelivery.com/accounts/USCDC/bulletins/1032201.

[206] ENDO-OR-CID-01343662.

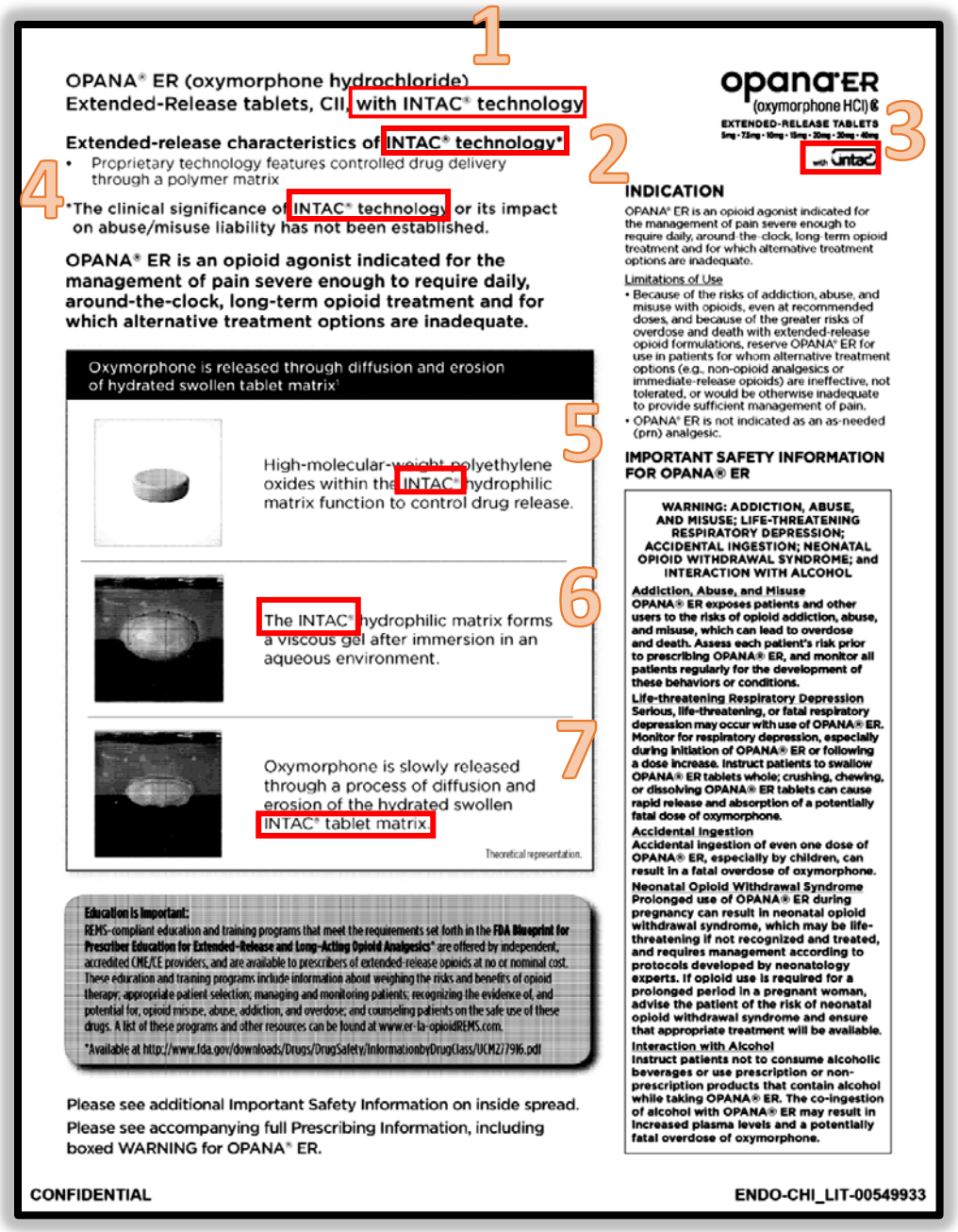
[207] ENDO-OR-CID-01343663.

defined "INTAC" as a "proprietary technology that features controlled drug delivery through a polymer matrix."[208]

169. Starting in September 2015, Endo sales representatives also distributed a "sell sheet" identified internally as "OP-02294b(1)" to health care providers, including those in Tennessee,[209] in which Endo used the term "Opana ER with INTAC" *seven* times in the main portion of the advertisement and stated elsewhere that "[t]he INTAC hydrophilic matrix forms a viscous gel after immersion in an aqueous environment." While the sell sheet included some warning information and stated "the clinical significance of INTAC® technology or its impact on abuse/misuse liability has not been established," the net impression from the ad was misleading, as Endo was previously warned by the FDA, and conveyed the claim that the Opana ER tablet stayed intact and was difficult to abuse by injection when this was not the case. Endo's sales representatives used this sell sheet during interactions with providers until at least March 24, 2017—only six months before Opana ER was pulled from the market entirely.

[208] ENDO-OR-CID-00002650.

[209] ENDO-OR-CID-01336352.



170. Endo also described Opana ER as "with INTAC" or "with INTAC Technology" in the following advertisements that were utilized during sales calls, given to health care providers, distributed to other health care entities, or otherwise used as advertisements:

- The OPANA ER Copay Slim Jim (OP-03289), which was used until April 23, 2017;

- The OPANA ER Pharmacy Sell Sheet (OP-02054f(2)), which was used until April 23, 2017;
- The DMVA Navigator (OP-02590j(1)), which was used until March 24, 2017;
- The OPANA ER Tablet Visual Guide (OP-02695(2)), which was used until April 23, 2017;
- The UnitedHealthcare Formulary Update Leave Behind (OP-04043), which was used until February 14, 2017; and
- The UnitedHealthcare Formulary Update LB Implementation Guide (OP-04043a), which was available until July 25, 2016.[210]

171. In Tennessee, Endo widely disseminated to health care providers and the public its claims that reformulated Opana ER was an abuse deterrent, had abuse deterrent properties, was crush resistant, remained intact, or was otherwise resistant to abuse. Further, Endo's claim that *Endo* pulled the original formulation of Opana ER from the market for safety reasons was also widely-disseminated and false when it was made.

172. Because these claims are express claims that involve health and safety, these are material claims upon which reliance is presumed.

173. Endo's claim that the reformulated Opana ER was an abuse deterrent, had abuse deterrent properties, was crush resistant, remained intact, or was otherwise resistant to abuse was false, misleading, and deceptive because it led health care providers and the public to believe that reformulated Opana ER had these attributes when this was not the case. Further, Endo's claim that it pulled the original formulation of Opana ER from the market because of safety concerns was false, misleading, and deceptive because it led health care providers and the public to believe that Endo had pulled the original formulation of Opana ER for safety concerns when it pulled the original formulation from the market because of monetary concerns.

[210] ENDO-OR-CID-01336352.

Safety Claims: Pseudoaddiction

174. Endo downplayed the problem of addiction by simply adopting the phony term "pseudoaddiction." Endo promoted this concept as part of the marketing for its opioid products in Tennessee when it was false, deceptive, and/or unsubstantiated.

175. From at least 2006 to 2013, Endo trained its sales representatives specifically to pitch pseudoaddiction,[211] which Endo's representatives then used in sales calls with providers.

176. In a 2006 sales training document, Endo taught its sales representatives that pseudoaddiction was a "term used to describe an iatrogenic phenomenon in which a patient with undertreated pain is perceived by healthcare professionals to exhibit behaviors similar to those seen in addiction but is not truly addicted[,]"[212] that "[t]he physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief[,]"[213] and that "[p]hysical dependence can be mistaken for addiction, because in some cases a patient may insist on continued use of the opioid even when pain has resolved, to avoid withdrawal symptoms experienced when they try to stop."[214]

177. In the same document, Endo tested its sales representatives and stated that "clock watching when waiting for the next opioid dose is a good example of a patient with . . . pseudoaddiction."[215]

---

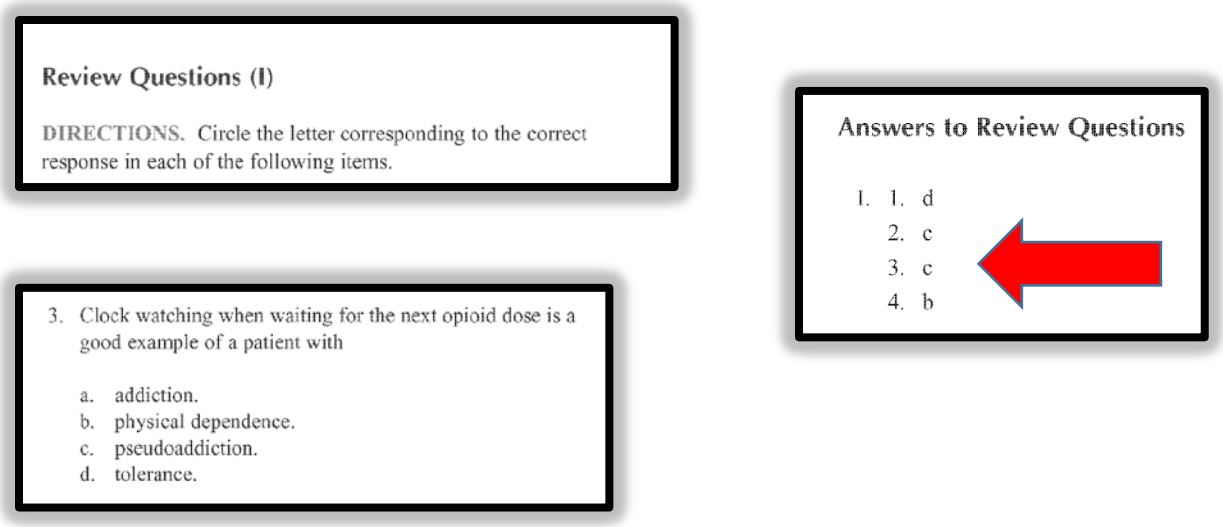
211 *See, e.g.*, ENT000082745, -746.

212 ENDO-OR-CID-00409556; ENT000082745, -746.

213 ENT000082746.

214 ENDO-OR-CID-00409557.

215 ENT000082753, -776.



178. Endo continued to push the fake science of pseudoaddiction in sales calls and specifically trained sales representatives to use pseudoaddiction in their interactions with health care providers. In a January 2011 sales training document, Endo instructed sales representatives that:

> Pseudoaddiction is a pattern of drug-seeking behavior among pain patients with unrelieved pain. Differentiating between addiction and pseudoaddiction can be challenging and may often take multiple patient encounters. One key difference from addiction is that in pseudoaddiction, the patient's drug-seeking behavior stops once his or her pain has been effectively treated.[216]

179. In a sales training document dated May 2013, Endo defined pseudoaddiction as "[a] pattern of drug-seeking behavior among pain patients with unrelieved pain, which can be differentiated from addiction by the stopping of the drug-seeking behavior once his or her pain has effectively been treated."[217] Similarly, Endo trained its sales representatives, including those in Tennessee, about pseudoaddiction in 2013—even though some of its Key Opinion Leaders

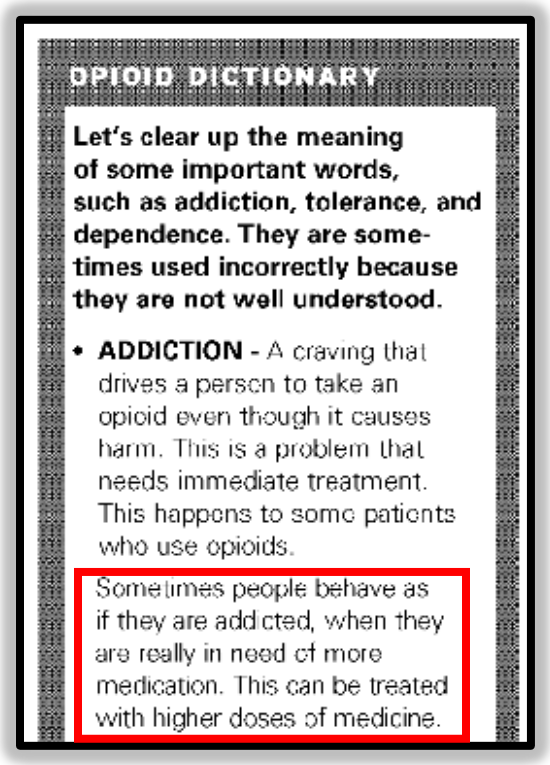
[216] ENDO-CHI_LIT-00545509.

[217] ENDO-OR-CID-00002491.

(KOLs), doctors hired by Endo to help spread its marketing messages to other providers, had publicly disavowed the concept in February 2012.

180. Endo KOL Dr. Lynn Webster[218] eventually admitted: "[Pseudoaddiction] obviously became too much of an excuse to give patients more medication. It led us down a path that caused harm. It is already something we are debunking as a concept."[219] And Endo's Vice President for Pharmacovigilance and Risk Management admitted that he was not aware of any research validating the "pseudoaddiction concept."[220]

181. Endo also funded and used third-party groups and websites to advance misleading marketing claims. The concept of pseudoaddiction was advanced on the Endo-sponsored www.painknowledge.org website including through the prominent statement that "*[s]ometimes people behave as if they are addicted, when they are really in need of more medicine. This can be treated with higher doses of medicine*" shown here.[221]



218 *See* ENDO-OR-CID-00335968.

219 John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom*, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

220 Assurance of Discontinuance, at 7, *In re Endo Health Solutions Inc.*, No. 15-228 (N.Y. Attorney General 2016), *available at* http://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

221 ENDO-OR-CID-00583388.

182. Endo concealed the fact that it was the predominant sponsor of www.painknowledge.org. Yet Endo repeatedly referred health care providers to this seemingly independent website in speaker's bureau meetings, linked to it on Endo's own marketing websites,[222] and referred to it as an "innovative, *independent* educational" website.[223]

183. Endo consistently used the pseudoaddiction concept in sales calls and written educational materials to teach providers in Tennessee to actually prescribe more or higher doses of opioids for their "pseudoaddicted" patients, who would then allegedly cease drug-seeking behavior once their pain was controlled. Endo taught its sales representatives, who in turn were teaching health care providers, that a "physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient's opioid dose to increase pain relief."[224] Endo used the pseudoaddiction concept as a deceptive way to persuade health care providers, many of whom were not specialists, to be more willing to treat patients with opioids.

184. Endo's pseudoaddiction claim was widely disseminated to health care providers and the public in Tennessee.

185. Because Endo's pseudoaddiction claim was an express claim that involves health and safety, it is material and reliance is presumed.

186. Endo's pseudoaddiction claim was false, misleading, and deceptive because it led health care providers and the public to believe that Endo's opioid products were safer than they actually were or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

---

222 ENDO-CHI_LIT-00537527.

223 ENDO-CHI_LIT-00537527.

224 ENDO-OR-CID-00409557.

Safety Claims: Misrepresentations as to Euphoria or "Peaks and Valleys"

187. Endo sought to minimize the true addictive potential of its opioid products by representing that its products provide a slow-onset, stable dose without the euphoria or "peaks and valleys" of other opioids—encouraging health care providers to infer that these opioids are safer because they do not produce the euphoric high that fosters addiction and abuse. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

188. In a 2007 document titled "*Better the Devil You Know* . . . Inspiring Physicians to Do the Right Thing with Opana ER," Endo's marketing people recommended that Endo advance the claim that Opana ER resulted in "less euphoria."[225] Later in the presentation, these consultants identified "less euphoria" as a concept that worked[226] and recommended that Endo build a marketing plan around the concept that "Opana ER controls pain the right way – with fewer strong side effects *and less euphoria*."[227]

189. Endo embraced this recommendation and used the "low incidence of euphoria" compared with other opioids as a marketing message for Opana ER,[228] which was identified as the "most important" topic discussed according to many health care providers surveyed following sales calls by Endo sales representatives in 2007.[229]

190. Endo continued this deceptive claim in 2008 when it selected "low rate of euphoria/CNS" as a key message for Opana ER shortly after its launch and continued to state that this was a reason to buy Opana ER.[230]

---

225 ENDO-OR-CID-01017684 (slides 8–9 of 120).

226 ENDO-OR-CID-01017684 (slides 15, 17 of 120).

227 ENDO-OR-CID-0107684 (slide 16 of 120) (emphasis added).

228 ENDO-CHI_LIT-00548031; *see also*, ENDO-CHI_LIT-00546699 (slides 7, 8 of 32).

229 ENDO-CHI_LIT-00547958, -8031, -8117.

230 ENDO-OR-CID-00596177 (slide 8 of 9).

191. Endo conducted an audit of Endo's sales calls in which health care providers were asked which sales message the Endo sales representative gave that resonated. Providers identified "fewer peaks and troughs" as a main message advanced by Endo sales representatives for Opana ER,[231] which was typically stated along with "reduced euphoria" claims. Endo deceptively used the "fewer peaks and troughs" message not to explain the long-acting component of Opana ER, but to claim that users experienced less of a high or euphoric effect compared to other opioids.

192. Endo also claimed that Opana ER resulted in less euphoria than OxyContin. These comparative claims were not supported by competent and reliable scientific evidence at the time they were made, as required by law.

193. Endo widely disseminated claims that Opana ER produced a lower rate of euphoria compared to other opioids to health care providers and the public in Tennessee.

194. Because Endo's claims that Opana ER users experienced a lower rate of euphoria compared to users of other opioids involves health and safety, they are material claims and reliance is presumed.

195. Endo's claims that Opana ER users experienced a lower rate of euphoria as compared to users of other opioids were false, misleading, and deceptive because they led health care providers and the public to believe that Opana ER was less attractive for abuse or less addictive than Opana ER actually was or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

[231] ENDO-CHI_LIT-00547958 (slides 16–17 of 136).

Safety Claims: Understating the Risk of Addiction

196. The vast majority of the "source of business" for Opana ER came from patients who continued to use the product. In internal documents, Endo stated that *continued users represented up to 88% to 89% of its total business from Opana ER*.[232]

197. In order to sell more of its opioid products and keep continued users on its products, Endo decided to change the narrative about the addictive potential of its opioids in ways that would generate less scrutiny from the FDA.

198. Endo's branded and unbranded marketing advanced this narrative through statements that misrepresented the true risk of addiction for Endo's opioid products. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

199. In sales calls, Endo sales representatives represented to providers that Opana ER had low addiction potential or otherwise understated the risk of addiction from Opana ER. As examples, Endo sales representatives stated that Opana ER "can provide pain relief throughout 24 hours, ensures good compliance, ensures low addiction potential,"[233] has "low risk of habituation,"[234] "improved efficacy with less tolerance,"[235] has "less euphoria and maybe less addictive potential,"[236] or made similar statements understating the risk of addiction.[237]

200. As early as 2004, Endo downplayed the risk of addiction to promote its opioids. Endo promoted in an unbranded marketing piece titled "Understanding Your Pain" that was targeted towards patients, among other things:

---

232 ENDO-CHI_LIT-00551611 (slide 31 of 41) (citing 88.3% continuation for source of business)); ENDO-OR-CID-00131870.

233 ENDO-CHI_LIT-00548030

234 ENDO-CHI_LIT-00548030.

235 ENDO-CHI_LIT-00548034.

236 ENDO-CHI_LIT-00548045.

237 ENDO-CHI_LIT-00548030 (e.g. "Also low risk of habituation.").

- "*Taking opioids for pain relief is not addiction. People addicted to opioids crave the opioid and use it regularly for reasons other than pain relief*."

- "*Addiction also IS NOT what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain*. This normal 'tolerance' to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, *it does not mean you will 'run out' of pain relief*. Your dose can be adjusted or another medicine can be prescribed."

- "Is it wrong to take opioids for pain? No. Pain relief is an important medical reason to take opioids as prescribed by your doctor. *Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction*."

- "How can I be sure I'm not addicted? Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, *maybe just to escape from your problems*."

- "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the rights reasons—to relieve your pain *and improve your function*. *You are not addicted*."[238]

201. Likewise, in 2006, Endo trained its sales representatives to tell providers that "[t]olerance can be mistaken for addiction because the patient may ask for increasing doses of the opioid, which can be perceived as 'drug-seeking behavior'"[239] and "[a]ddiction is a disorder and not an expected consequence of taking an opioid."[240]

202. Endo's branded website for Opana and Opana ER, www.opana.com, misrepresented the risk of addiction. It stated:

> Most doctors who treat patients with pain agree that patients treated with prolonged medicines usually do not become addicted. Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal

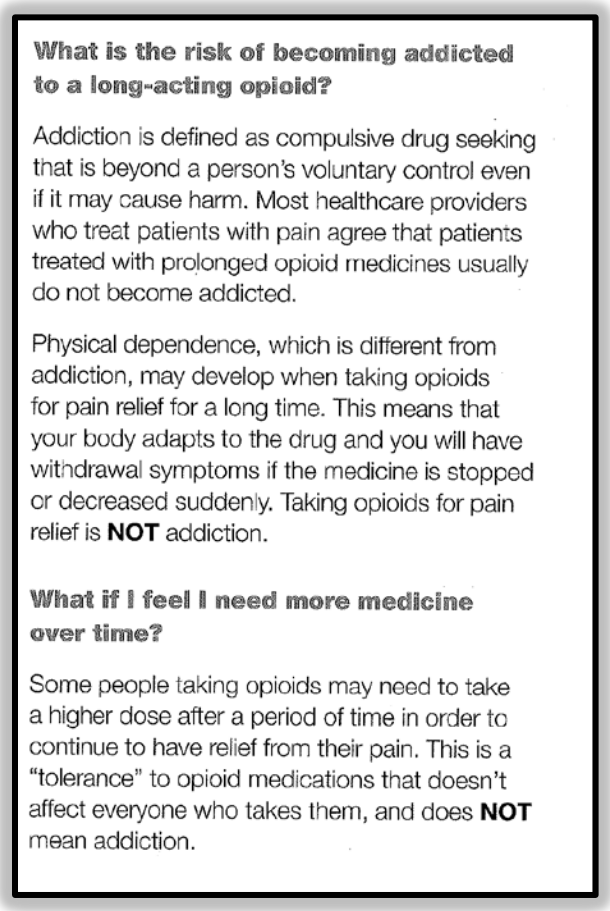
[238] https://perma.cc/QN86-62PK (emphasis added).

[239] ENT000082746.

[240] ENT000082748; *see also*, ENDO-OR-CID-00409559.

symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is NOT addiction.[241]

203. Endo also widely circulated a promotional brochure for its opioids titled "Information on Taking a Long-Acting Opioid" in 2008 and 2009 that stated:[242]



What is the risk of becoming addicted to a long-acting opioid?

Addiction is defined as compulsive drug seeking that is beyond a person's voluntary control even if it may cause harm. Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.

Physical dependence, which is different from addiction, may develop when taking opioids for pain relief for a long time. This means that your body adapts to the drug and you will have withdrawal symptoms if the medicine is stopped or decreased suddenly. Taking opioids for pain relief is **NOT** addiction.

What if I feel I need more medicine over time?

Some people taking opioids may need to take a higher dose after a period of time in order to continue to have relief from their pain. This is a "tolerance" to opioid medications that doesn't affect everyone who takes them, and does **NOT** mean addiction.

204. Endo made "Information on Taking a Long-Acting Opioid" accessible to providers and patients in Tennessee and nationwide on its www.opana.com website[243] until at least 2011.[244] Endo also included "Information on Taking a Long-Acting Opioid" in the Opana ER rebate kit

241 ENDO-CHI_LIT-00537608.

242 ENDO-CHI_LIT-00538443, ENDO-CHI_LIT-00541197 (emphasis in original).

243 ENDO-CHI_LIT-00537579.

244 ENDO-OR-CID-00089341.

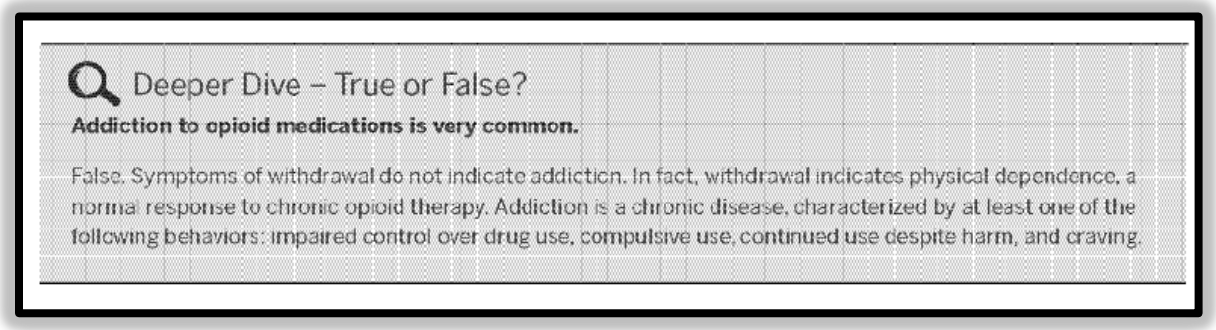
that Endo distributed to providers, pharmacies, and ultimately consumers at least until March 31, 2011.[245]

205. Endo never conducted a study or other survey with health care providers who treat patients with pain to determine whether the providers agreed with the claims that patients treated with prolonged opioid medicines usually do not become addicted. Endo does not have competent and reliable scientific evidence to support such claims at the time they were made.

206. Endo also deceptively trained its sales representatives that physical dependence and addiction could be easily distinguished from one another. Endo's sales representatives, in turn, trumpeted this message to health care providers.

207. In a 2010 training guide, Endo instructed its sales representatives to inform providers that opioid analgesics were potentially addictive but "[l]ong-term opioid use can induce physical dependence and may induce tolerance to therapy. None of these physiological phenomenon cause addiction."[246]

208. Between 2010 and 2015, Endo trained its sales representatives who made sales calls to health care providers, including those in Tennessee, that it was "false" that addiction to opioid medications is very common, stating the following:[247]


Deeper Dive – True or False?

Addiction to opioid medications is very common.

False. Symptoms of withdrawal do not indicate addiction. In fact, withdrawal indicates physical dependence, a normal response to chronic opioid therapy. Addiction is a chronic disease, characterized by at least one of the following behaviors: impaired control over drug use, compulsive use, continued use despite harm, and craving.

245 ENDO-OR-CID-00089341.

246 ENDO-CHI_LIT-00545277.

247 ENDO-CHI_LIT-00545278; ENDO-CHI_LIT-00556839.

209. Endo's claims that understated the risk of addiction from opioids were widely disseminated to health care providers and the public in Tennessee.

210. Because Endo's claims concerning the risk or relative risk of addiction involve health and safety, they are material and reliance is presumed.

211. Endo's claims that understated the risk of addiction were false, misleading, and deceptive because it led health care providers and the public to believe that Endo's opioid products were safer or less addictive than they actually were or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

Safety Claims: Misrepresenting the Efficacy of Tools to Mitigate Addiction

212. In order to increase health care providers' willingness to prescribe its addictive opioids, Endo misrepresented the efficacy of abuse and diversion mitigation tools like patient contracts, urine drug testing, pill counts, and similar strategies. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

213. These claims were especially harmful because Endo's sales representatives made them to nurses, physician assistants, general practitioners, internists, and family doctors who, generally speaking, lack the time and expertise to closely manage higher-risk patients on opioids.

214. Moreover, these misrepresentations were critical to assure the health care providers who were beginning to see or hear about the rising tide of opioid addiction that they could safely prescribe opioids in their own practices and that addiction was avoidable—such issues were instead the result of other providers' failure to rigorously manage and weed out problem patients.

215. In order to make patients more willing to take its addictive opioids, Endo made these claims to the public, including physicians and patients, in Tennessee and nationwide through

a website Endo operated called www.endopromise.com. These statements were false, deceptive, and/or unsubstantiated at the time they were made.

216. The 2016 Centers for Disease Control Guideline for Prescribing Opioids for Chronic Pain[248] (2016 CDC Guideline) confirms the lack of adequate substantiation to support Endo's claims regarding the utility of screening tools and patient management strategies in managing addiction risk. The 2016 CDC Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse, or misuse."[249] As a result, the 2016 CDC Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients at low or high risk for [opioid] abuse or misuse" and instructs that health care providers "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[250]

217. In marketing to health care providers in person and through www.endopromise.com, which was linked through Endo's main branded product website, www.opana.com,[251] Endo offered the "PROMISE Initiative" as one of these programs. Endo described it as "one more example of Endo's ongoing collaboration . . . to ensure patients have appropriate medical access to opioid analgesics for pain relief while also *having the means to minimize the potential inherent risks of these medications*."[252] Through its PROMISE initiative

---

248 McDowell, Deborah, MD, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, CENTERS FOR DISEASE CONTROL AND PREVENTION, 65(1), *available at* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm (hereinafter 2016 CDC Guideline).

249 2016 CDC Guideline, at 11.

250 2016 CDC Guideline, at 28.

251 ENDO-CHI_LIT-00537607.

252 https://web.archive.org/web/20060815215028/http://www.endopromise.com:80/default.aspx (Aug. 15, 2006 to at least Mar. 6, 2009) (emphasis added).

and elsewhere, Endo referenced several different mitigation tools in sales calls for Opana ER to health care providers.[253]

218. Endo utilized the promotion of the PROMISE initiative as part of its "OPANA Brand Positioning" to "Reduce the Complexities of Managing Chronic Moderate to [Severe] Pain."[254] The PROMISE initiative was such an integral part of Endo's marketing that it used "Promise Initiative" as one of its default messages for sales representatives to select in describing what messages were delivered in sales calls with providers.[255]

219. Elsewhere, Endo described its PROMISE initiative as providing "access to practical tools for health care professionals that are designed to support the appropriate and responsible use of opioid analgesics,"[256] "minimizing the inherent risks of misuse, abuse, and diversion of these medications[,]"[257] and providing "a proactive approach to managing the potential risks inherent in opioid therapy."[258]

220. Endo funded and promoted the Screener and Opioid Assessment for Patients with Pain (SOAPP) as a self-reporting tool to determine whether a person is likely to become addicted to opioids. Endo promoted SOAPP through its PROMISE initiative.

221. Endo represented SOAPP as "likely to predict which patients would require more or less monitoring on long-term opioid therapy"[259] and a tool "for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require."[260]

---

253 ENDO-OR-CID-01293715.

254 ENDO-CHI_LIT-00547048 (slide 18 of 32).

255 ENDO-OR-CID-00459065 (Opana ER tab).

256 ENDO-OR-CID-00414694 (slide 33 of 34).

257 https://web.archive.org/web/20060815215028/http://www.endopromise.com:80/default.aspx (Aug. 15, 2006).

258 https://web.archive.org/web/20060815215028/http://www.endopromise.com:80/default.aspx (Aug. 15, 2006).

259 ENDO-OR-CID-00146555.

260 ENDO-OR-CID-146555.

222. Endo presented SOAPP as an effective risk mitigation tool that health care providers could confidently rely upon and that could *predict* aberrant medication-related behavior. Endo's SOAPP tool even provided a purported "positive *predictive* value" based on responses to the 24 questions:[261]

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	2.53	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

223. Among other things, Endo's SOAPP tool stated:

- Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients like to have few problems on long-term opioid therapy from those requiring more monitoring[; and][262]

- All 24 questions contained in the SOAPP®-R *have been empirically identified as predicting aberrant medication-related behavior* six months after training[.][263]

224. Endo utilized another ineffective tool known as the Current Opioid Misuse Measure or "COMM," which was a brief patient self-assessment survey to monitor chronic pain patients.[264] Endo described its COMM as "[i]deal for documenting decisions about the level of monitoring

261 ENDO-OR-CID-00146558 (emphasis added).

262 ENDO-OR-CID-00146555.

263 ENDO-OR-CID-00146558 (emphasis added).

264 ENDO-OR-CID-00146527.

planned for a particular patient or justifying referrals to specialty pain clinic[s]"[265] and stated that the tool "has undergone initial validation."[266]

225. Endo advocated use of both SOAPP and COMM as "Best Practices in Opioid Prescribing for Risk Management" in marketing for its opioids, including template slides for Endo's paid Speakers' Bureau program.[267]

226. In addition to its PROMISE Initiative, Endo also used screening tools as part of its marketing efforts to health care providers including on www.opana.com.[268]

227. Endo planned for its "Commercial Team" to distribute a pain clinic algorithm package that included a patient contract and toxicology screening to health care providers Endo's sales representatives called upon.[269]

228. Endo overstated the efficacy of its risk mitigation tools to help providers evaluate their patients' relative risk for addiction or other problems from taking opioids.

229. Endo's overstatements about the efficacy of its risk mitigation tools to minimize the risks of addiction and other problems were widely disseminated to health care providers and the public in Tennessee.

230. Because Endo's overstatements about the efficacy of its risk mitigation tools were express claims that involve health and safety, they are material and reliance is presumed.

231. Endo's overstatements about the efficacy of its risk mitigation tools to minimize the risks of addiction and other problems were false, misleading, and deceptive because they led health care providers and the public to believe that these risk mitigation tools were more effective

---

265 ENDO-OR-CID-00146527.

266 ENT000066121.

267 ENDO-OR-CID-00462039 (slide 32 of 34).

268 *See* ENDO-OR-CID-00089342.

269 ENT000100256, -57.

than they actually were at assessing a patient's risk for overdose, addiction, abuse, or misuse or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

Failing to Disclose Increased Risk of Addiction at Higher Doses

232. As recognized by the CDC and the National Institutes of Health's National Institute on Drug Abuse, taking opioids for longer periods of time or in higher strength doses increases the risk of addiction, among other serious risks and side effects like overdoses and death.[270]

233. Nevertheless, Endo represented that the dosage for its opioid products could be increased without disclosing the material fact that this would increase the risk of addiction, among other serious risks and side effects.

234. Endo distributed a pamphlet in 2004 titled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which targeted patients and stated that they "won't 'run out' of pain relief" so long as they increase their dosages, but did not disclose the increased risk of addiction, among other risks and side effects. Endo made *Understanding Your Pain* available on its website and the pamphlet was intended to reach Tennessee prescribers and patients among others.[271]

235. Likewise, as part of its marketing efforts for its opioid products including Opana ER, Endo distributed a book written by paid KOL Dr. Lynn Webster titled *Avoiding Opioid Abuse While Managing Pain*, which stated that in the face of signs of aberrant behavior, increasing the dose "*in most cases … should be the clinician's first response*,"[272] again without appropriately disclosing the increased risk of addiction from higher doses.

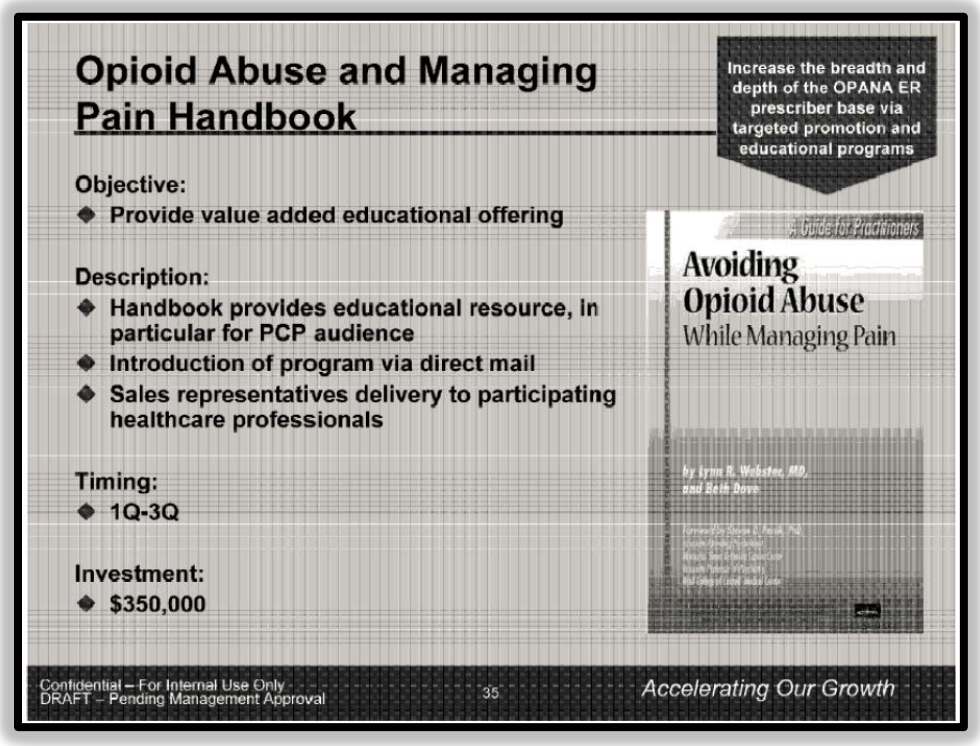
---

[270] *Opioid Prescribing: Where You Live Matters*, CENTERS FOR DISEASE CONTROL AND PREVENTION, *available at* https://www.cdc.gov/vitalsigns/opioids/index.html; *Opioid Prescribers Can Play a Key Role in Stopping the Opioid Overdose Epidemic*, NATIONAL INSTITUTE ON DRUG ABUSE, *available at* https://www.drugabuse.gov/publications/improving-opioid-prescribing/improving-opioid-prescribing.

[271] https://perma.cc/QN86-62PK.

[272] ENDO-CHI_LIT-00538765 (emphasis added).

236. Endo used Dr. Webster's book as an integral part of its marketing efforts. A slide from an Opana ER business plan contemplated distribution of the book as part of Endo's efforts to "[i]ncrease the breadth and depth of the OPANA ER prescriber base via targeted promotion and educational programs." The slide indicates that the book *Avoiding Opioid Abuse While Managing Pain* would be particularly effective "for [the] P[rimary] C[are] P[hysician] audience" and Endo instructed "[s]ales representatives [to] deliver [the book] to participating health care professionals." The slide, shown below, demonstrates Endo's use of information in this book authored by a paid KOL in its branded marketing strategy:[273]



237. Internal Endo documents indicate that the company distributed copies of *Avoiding Opioid Abuse While Managing Pain* to providers between 2008 and at least 2011.[274] Based on the

[273] ENDO-CHI_LIT-00541079; ENDO-CHI_LIT-00546435 (slide 64 of 86).

[274] ENT000066123, -124; ENDO-OR-CID-00081597; ENDO-CHI_LIT-00538910; ENDO-OR-CID-00012883.

nationwide and uniform character of Endo's marketing as well as the book's approval for distribution, this book was made available to and was intended to reach Tennesseans as part of Endo's own marketing efforts.

238. In a sales promotion to health care providers, including those in Tennessee, Endo offered free copies of the book *Avoiding Opioid Abuse While Managing Pain* and a brochure about Opana ER's co-pay.[275]

239. Endo actually represented its distribution of the book *Avoiding Opioid Abuse While Managing Pain* to health care providers it called on as part of its abuse deterrence efforts nationwide.[276]

240. As of 2010, all of Endo's East Tennessee sales representatives distributed copies of this book to health care providers in Tennessee.[277]

241. In addition to express misrepresentations, Endo also downplayed the increased risk of addiction from higher doses of its opioid products through material omissions.

242. In its marketing, including of branded materials, of unbranded materials, and in sales calls with health care providers and others in Tennessee, Endo failed to disclose the material fact that there is an increased risk of addiction at higher doses of its opioid products.

243. The ability to escalate doses was critical to Endo's efforts to market opioids for the long-term treatment of chronic pain. Unless health care providers felt comfortable prescribing increasingly higher doses of opioids to counter their patients' building tolerance to the drug's effects, they may have discontinued opioid therapy or chosen not to initiate it at all. Moreover, without disclosing the increased risk of addiction, Endo regularly encouraged providers in

[275] ETN000051694.

[276] ENDO-OR-CID-00147537.

[277] ENDO-OR-CID-00184851.

Tennessee to increase the dose of its opioid products like Opana ER, or "titrate up," rather than prescribe them more frequently.

244. High-dose opioids were a perpetual and significant part of Endo's business in Tennessee—particularly Opana ER. Endo sold disproportionately high amounts of its 20, 30, and 40 mg tablets of Opana ER.

245. To put this in context, one Opana ER 20 mg tablet taken every 12 hours equates to 120 MMEs per day—with an MME being a standardized unit of opioid potency.[278] This dosage is 30 MMEs *over* the daily threshold that the 2016 CDC Guideline recommends providers should avoid or carefully justify.[279]

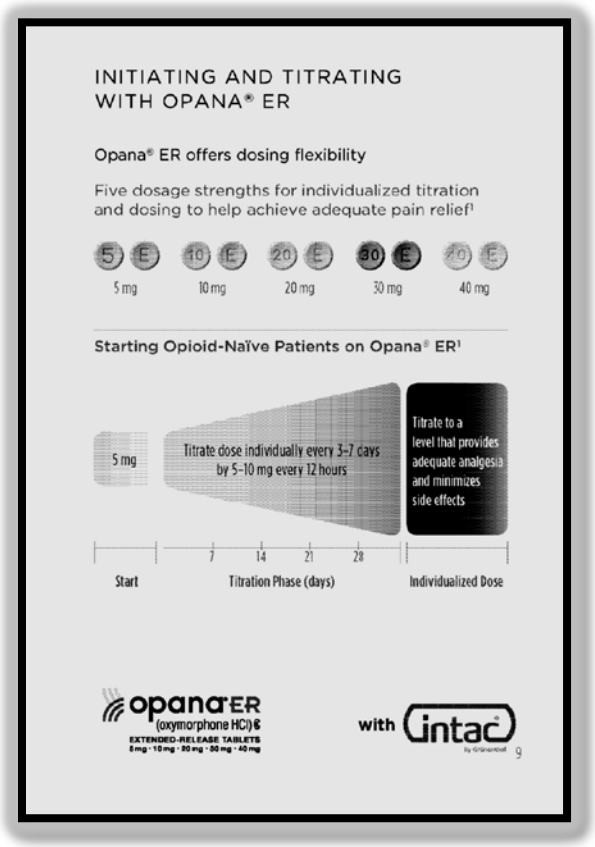
246. From 2007 to 2014, Endo sold at least *1,819,584,028* MMEs of Opana ER in Tennessee with *86.5%* of that coming from high-dose Opana ER (20 mg or higher).[280] Of the 25,779,741 tablets of Opana ER prescribed in Tennessee between 2007 and 2014, 17,797,992 or *69%* of these units were high dose.[281] Likewise, of the approximately 424,536 prescriptions written for Opana ER in Tennessee from 2007 to 2014, 282,970 or *67%* of these prescriptions were for high-dose Opana ER (20 mg or higher).[282]

247. Endo made the escalating dose strengths a core piece of its marketing for Opana ER, stating, "Five dosage strengths for individualized titration and dosing to help achieve adequate pain relief."[283] Elsewhere, Endo encouraged providers to start patients at a 5 mg dose of Opana

[278] https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME_Conversion_Chart.pdf
[279] https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.
[280] ENDO-OR_MASS_CIDS-0000047.
[281] ENDO-OR_MASS_CIDS-0000047.
[282] ENDO-OR_MASS_CIDS-0000047.
[283] ENDO-OR-CID-00006271.

ER and titrate the dose upwards every 3–7 days by 5–10 mg every 12 hours[284] and pushed the idea that "[h]igher doses of oxymorphone ER did not appear to be associated with a marked worsening of tolerability."[285]

248. Numerous Endo marketing materials for Opana ER, such as the example below, that were widely disseminated in Tennessee, depict the different tablet strengths—in a line—and instruct health care providers that they can increase the dose by titrating upwards without disclosing the increased risk of addiction at higher doses.[286] As seen in the bottom right-hand corner, the Opana ER ad also includes the phrase "with intac," which Endo deceptively used to imply that Opana ER tablets could not be crushed.



284 ENDO-CHI_LIT-00549982.

285 ENDO-OR-CID-00256289.

286 ENDO-OR-CID-00006271.

249. Endo failed to disclose the increased risk of addiction at higher opioid doses in marketing and promotional materials for its opioid products that were widely disseminated to health care providers and the public in Tennessee.

250. Because the omission involves health and safety, it is material and reliance is presumed.

251. Endo's marketing and promotional materials that failed to disclose the increased risk of addiction at higher doses were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products were safer than they actually were and did not have an increased risk of addiction at higher doses.

Failing to Disclose Lack of Evidence for Long-Term Use of Opioids

252. To convince Tennessee health care providers and patients that opioids should be widely used to treat chronic pain, despite the unavoidable risk of addiction, Endo had to persuade them that there is a significant upside to long-term opioid use. The problem was Endo had no evidence to support this, but that did not stop the company from making the deceptive claims.

253. This lack of substantiation for long-term use has been acknowledged by the FDA, which stated that it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."[287] The 2016 CDC Guideline also makes clear there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled

[287] Ltr. from U.S. Food and Drug Administration to Andrew Kolodny, M.D., Physicians for Responsible Opioid Prescribing, 10 (Sept. 10, 2013), *available at* http://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf.

randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[288]

254. Similarly, the U.S. Health and Human Services Agency for Healthcare Research and Quality released an Evidence Report that assessed the current evidence on effectiveness and harms of opioid therapy for chronic pain focusing on long-term (≥1 year) outcomes and concluded that the evidence is "very limited but suggests an increased risk of serious harms that appears to be dose-dependent."[289]

255. Endo has long been aware of the disconnect between the academic literature and the reality—which it helped create—that many patients take its opioids for months or years.

256. Endo even acknowledged in 2012 that "[t]here is a lack of clinical trial data supporting safety of high-dose (>180 mg/d of morphine equivalents) opioid administration in the patient *with chronic pain* treated over an extended period."[290]

257. Nevertheless, Endo built on its earlier marketing and continued to tout the purported benefits of long-term opioid use, while falsely and misleadingly implying that these benefits are supported by scientific evidence.

258. In training documents from 2006, Endo told its sales representatives that:

> [p]atients treated with prolonged opioid therapy do not usually develop addictive disorders, though the actual risk is unknown and likely varies with genetic disposition, among other factors.[291]

---

288 2016 CDC Guideline at 15, 19.

289 Roger Chou, M.D., F.A.C.P., *The Effectiveness and Risks of Long-Term Opioid Treatment of Chronic Pain*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY; U.S. DEPARTMENT OF HEALTH AND HUMANS SERVICES, abstract *available at* https://www.ncbi.nlm.nih.gov/books/NBK258809/.

290 ENDO-OR-CID-00256289 (emphasis added).

291 ENT000082747; *see also*, ENDO-OR-CID-00409558.

259. Endo's branded marketing materials also promoted long-term use of its opioid products without disclosing the absence of long-term studies. In an audit of messages health care providers recalled from visits by Endo sales representatives, Endo documented the "long duration of action/long acting" as one of its main messages.[292]

260. Likewise, on www.opana.com, Endo stated in partial response to the question "What is the risk of becoming addicted to a long-acting opioid?" that "Most doctors who treat patients with pain agree that patients treated with *prolonged* opioids medicines usually do not become addicted."[293] Endo failed to disclose it had no studies about long-term use or any surveys or studies of doctors who treat pain patients assessing the accuracy of the statement that "patients treated with prolonged opioid medicines usually do not become addicted."

261. To further push its opioid products, Endo even distributed a misleading pamphlet to the public titled "Information on Taking a Long-Acting Opioid" that stated among other things: "If tolerance develops it does not mean you will run out of pain relief. Your healthcare provider can adjust your dose or prescribe another medicine" without disclosing the absence of long-term studies."[294]

262. In sales trainings, Endo sales representatives were not trained to make full and complete disclosure about the lack of evidence supporting long-term opioid use. In addition, in preparation for interactions with doctors, Endo trained its sales representatives that studies lasting 12 weeks "demonstrated the long-term efficacy of OPANA® ER" without disclosing the absence of long-term studies.[295]

---

[292] ENDO-CHI_LIT-00547959 (slide 17 of 136).

[293] ENDO-CHI_LIT-00537608.

[294] ENDO-CHI_LIT-00542736; ENDO-OR-CID-00143059; *see also*, ENDO-OR-CID-00080699; ENDO-OR-CID-00143054.

[295] ENDO-OR-CID-00782410.

263. Endo failed to disclose the lack of substantiation for long-term use in each marketing and promotional material for its opioid products that were widely disseminated to health care providers and the public in Tennessee.

264. Because the omission involves health and safety, it is material and reliance is presumed.

265. Endo's marketing and promotional materials that failed to disclose the lack of substantiation for use of opioids for long-term treatment were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products were studied for a longer period of time than they actually were.

Safety Claims: General Safety Claims

266. Endo made a series of sweeping safety claims in Tennessee that represented the company's opioid products as safer than they actually were. These claims were false, deceptive, and/or unsubstantiated at the time they were made.

267. As early as 2004, Endo made claims that understated the risks of side effects from taking opioids in its promotional materials which were made accessible to patients and others in the public, including Tennessee. Endo stated, among other things:

> What can I do about side effects? Talk to your doctor, nurse, or pharmacist about the side effects of opioids. *If they occur, remember that most opioid side effects can be treated or prevented*.[296]

268. In another part of the same promotional piece, Endo sought to minimize the potential side effects of opioids through a "Pain Control Record" that disingenuously emphasized "drowsy" and "upset stomach" as representative side effects from opioid use.[297]

[296] https://perma.cc/QN86-62PK.

[297] https://perma.cc/QN86-62PK.

269. Endo knew that sweeping claims about the safety of Opana ER worked to increase sales. In a 2007 document titled "*Better the Devil You Know . . . Inspiring Physicians to Do the Right Thing with Opana ER*," Endo's marketing consultant recommended a marketing campaign built around these concepts:

> Opana ER:
> Control Pain The Right Way
>
> Chronic pain can disconnect you from the important parts of life like friends and family. An opioid pain reliever is often the best option. But these medicines come with a lot of baggage, like strong side effects, interactions with other drugs – not to mention the abuse that we hear about in the news.
>
> *Opana ER was designed around these issues, so you can get the most effective and long lasting pain relief, with less baggage.* Most ER opioids (like OxyContin) release in a burst – creating euphoria that fades away over time into breakthrough pain. Opana ER is different. Its molecule and release matrix provide smoother, more consistent pain control for 12 hours, with less dizziness, *fewer side effects* and drug interactions. Plus, less euphoria means it's an unattractive target for abusers.
>
> Opana ER controls pain the right way – with fewer strong side effects and less euphoria.[298]

270. Endo made generalized safety claims about its opioid products in line with this recommended messaging.

271. Endo's messaging worked. In 2008, Endo confirmed that health care providers perceived "safety/tolerability/fewer side effects" as an advantage of Opana ER, including that it had a purported low abuse potential, lower incidence of side effects, and lower drug interactions.[299] Endo quickly capitalized on this perceived advantage.

272. Endo sales representatives misrepresented Opana ER's safety in sales calls. As illustrative examples, Endo's sales representatives told health care providers that Opana ER "has

---

[298] ENDO-OR-CID-001017684 (slide 16 of 120) (emphasis added).

[299] ENDO-CHI_LIT-00545918 (slide 20 of 23).

minimal side effects,"[300] "less risk of narcotic related problematic and concerning side effects,"[301] and "does not cause a drug overdose or excessive sleepiness or excessive number of side effects[.]"[302]

273. Endo published other claims in sales materials to make opioids seem safer than they actually are. For example, one of Endo's sales promotions stated, "Slowed breathing is very rare when oral opioids are used appropriately for pain relief."[303]

274. Endo instructed its sales representatives in training documents for their interactions with health care providers:

> *As you may recall from the Introduction Module, a number of misconceptions and fears about the use of opioid analgesics can contribute to the undertreatment of patients with chronic pain*. In your conversations with customers, it will be important for you to appreciate their concerns and provide thoughtful evidence-based answers to address their questions when appropriate. You can also gain credibility with customers and show integrity by acknowledging when you are unable to provide an answer. By acting as a reliable OPANA® ER product resource, your knowledge and balanced perspective will be trusted and provide valuable support to your customers.[304]

275. Endo's sales representatives in Tennessee were praised by the company's consultants for "[c]linical differentiation *based on safety*" as "the key messaging to drive differentiation and fuel growth" for Opana ER.[305] In an internal e-mail referring to "clinical differentiation based on safety," Endo's marketing consultant stated:

> It may be inspiring to give a "shout out" to reps who are experiencing success with this strategy – e.g. [three sales representatives] in the north Knoxville – Opana ER share has surpassed OxyContin – don't know exactly what's driving their success[.][306]

---

300 ENDO-CHI_LIT-00548041.

301 ENDO-CHI_LIT-00548117.

302 ENDO-CHI_LIT-00548072.

303 ENDO-CHI_LIT-00538446.

304 ENDO-OR-CID-00782419 (emphasis added).

305 ENDO-OR-CID-00189249 (emphasis added).

306 ENDO-OR-CID-00189249.

276. Endo continued to make deceptive safety claims about Opana ER as part of its core marketing message. In the document titled "OPANA ER Growth Trends Issue – Market Research Final Report," Endo stated the following:

- Aggressive detailing having an impact

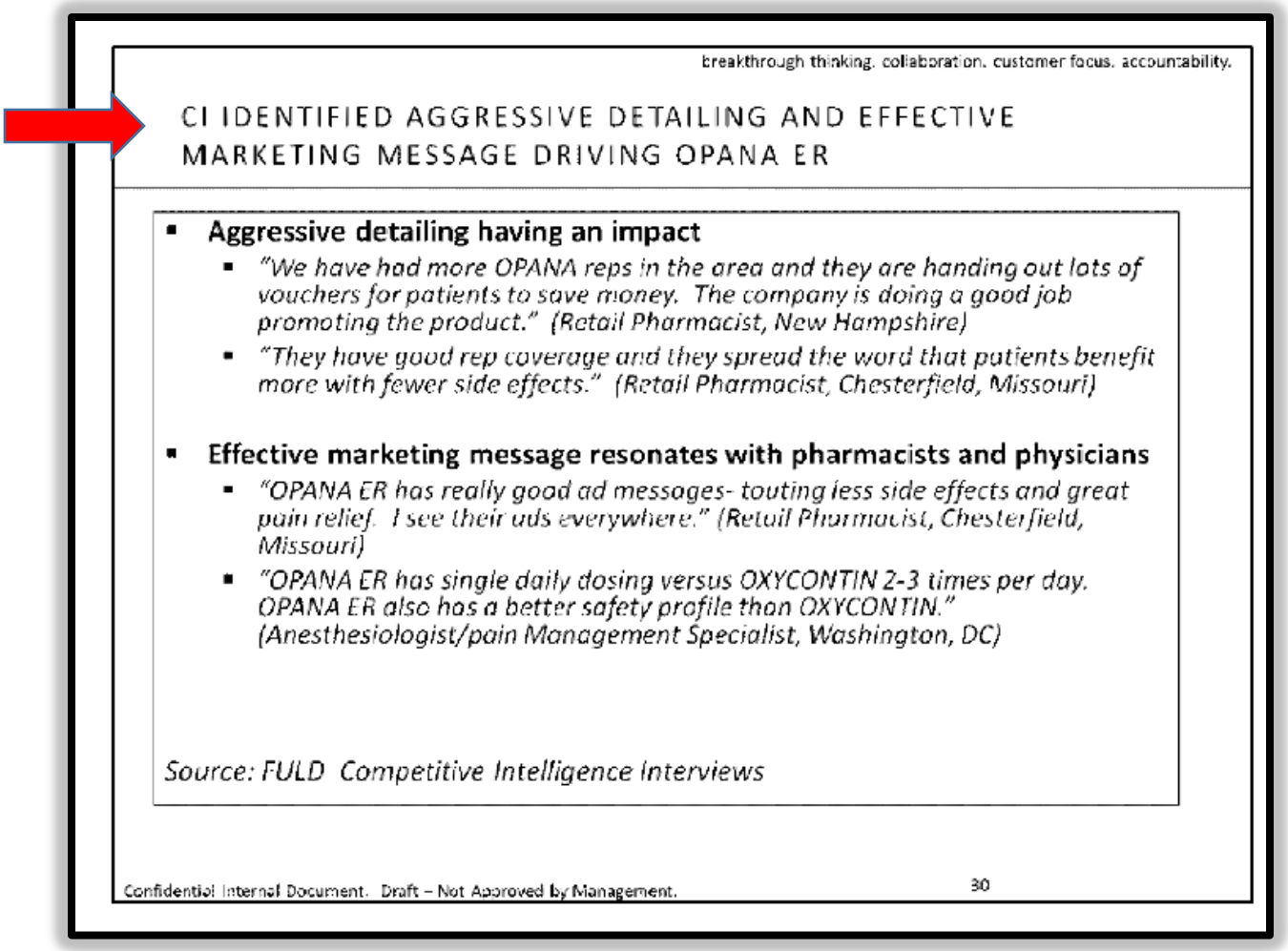
  ….

  - 'They have good rep coverage and they spread the word *that patients benefit more with fewer side effects*.' (Retail Pharmacist, Chesterfield, Missouri)

- Effective marketing message resonates with pharmacists and physicians
  - 'OPANA ER has really good ad messages – *touting less side effects* and great pain relief. I see their ads everywhere.' (Retail Pharmacist, Chesterfield, Missouri)

  - 'OPANA ER has single daily dosing versus OXYCONTIN 2-3 times per day. OPANA ER also *has a better safety profile than OXYCONTIN*.' (Anesthesiologist/pain Management Specialist, Washington, DC)[.][307]

[307] ENDO-OR-CID-00182471 (document says "draft," but was actually presented internally; *see* ENDO-OR-CID-00182441) (emphasis added).



277. Endo's sweeping safety claims about its opioid products were widely disseminated to health care providers and the public in Tennessee.

278. Because the claims involve health and safety, they are material claims and reliance is presumed.

279. Endo's sweeping safety claims about its opioid products were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products were safer than they actually were or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

B. DECEPTIVE COMPARATIVE CLAIMS

280. From the beginning, Endo worried that its opioids, including Opana ER, would be perceived as "me-too" drugs that would have trouble establishing market share.[308] By the time Endo launched Opana ER in 2006, Purdue had created the extended release opioid market for chronic pain through OxyContin and had a 10-year head-start. Though Endo knew that it could not make comparative claims about its competitors' opioids in the absence of head-to-head studies of its drug and a competitor's drug, Endo routinely did so anyway to try to increase market share within the long-acting opioid segment—a market that Endo defined as including OxyContin, generic controlled release oxycodone, Avinza, Kadian, and all other Sustained Release Morphine.[309]

281. Endo knew that it was deceptive to make unsubstantiated comparative claims. In internal documents, the company acknowledged:

> Sales representatives should not make comparative claims unless such claims have been approved by the Marketing & Advertising Review Committee (MARC). Examples of inappropriate comparative claims include:
>
> - Label-to-label comparisons (e.g., 'Drug A's clinical study showed 80% clinical response but Drug B's clinical study showed 65% clinical response if you look at their respective labeling')[;]
>
> - Comparisons of pharmacokinetic or pharmacodynamic effects to show greater efficacy (e.g. 'Drug A works better, because it has a longer half-life than Drug B')[;]
>
> - Comparisons or pharmacokinetic or pharmacodynamic effects to show greater safety (e.g.., 'Drug A is safer than Drug B, because it has a shorter half-life than drug B')[; and]

[308] ENDO-CHI_LIT-00545916 (slide 22 of 65); *see* also, ENDO-CHI_LIT-00543590.

[309] ENDO-CHI_LIT-00545553 (slide 15 of 39).

- Claims about a drug's uniqueness to imply superior efficacy or safety without a head-to-head trial comparing your drug to the drug(s) it is unique compared to (e.g., 'unique efficacy in elderly patients')[.][310]

282. Endo also recognized in internal documents that promotional materials are:

> false and misleading if they state or suggest that a drug's safety or effectiveness is comparable or superior to another drug without "substantial evidence" to support such a claim. A comparative claim must be backed up by at least 2 adequate, well-controlled studies in which the drugs are compared head-to-head, using comparable dosage regimens, or by a single, well-controlled study. Similarly, because of the differences in trial designs, inclusion criteria, and other factors, it is not permissible to compare results from 2 noncomparative trials.[311]

283. While approval for a drug's use on its label requires clinical testing, most often this consists of a study of that drug and a placebo. Head-to-head trials are costly and may result in adverse findings that have to be disclosed to regulators. Consequently, head-to-head trials are not often funded by pharmaceutical companies.

284. Endo did not have any rigorous comparative clinical data for Opana ER. In an internal Frequently Asked Questions response sheet given to sales representatives for sales calls with health care providers, Endo admitted "There are no direct comparison studies of [reformulated Opana ER] to other opioid analgesics."[312]

285. Elsewhere, Endo cited a lack of "head-to-head data" as a barrier to greater market share acquisition and the "lack of differentiation data" as a challenge to addressing the "#1 Key Issue" of product differentiation in an Opana ER brand strategy plan.[313]

286. This dynamic posed a problem for Endo. The company had no rigorous head-to-head studies, but still needed compelling reasons to get health care providers who were prescribing

---

310 ENDO-OR-CID-00782391.

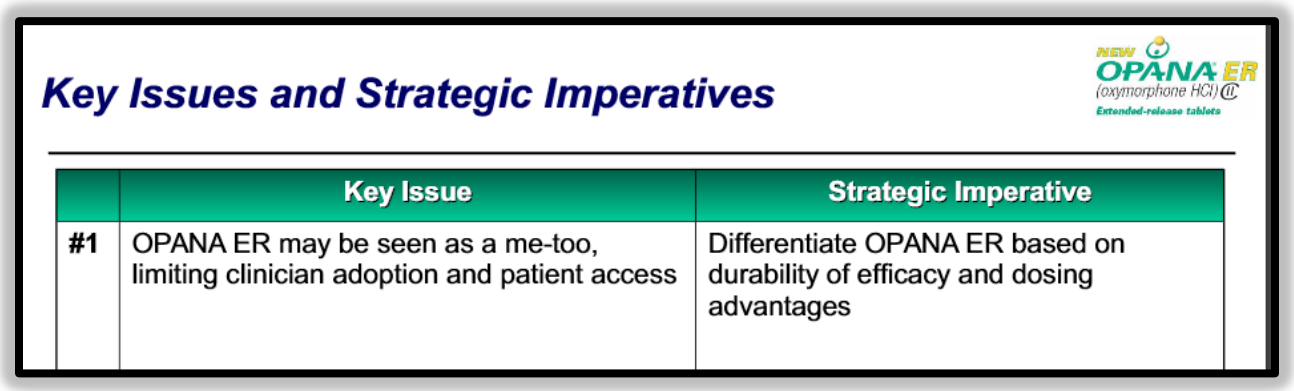
311 ENT000082032.

312 ENDO-OR-CID-00474380.

313 ENDO-CHI_LIT-00541024.

OxyContin and other extended release competitors to switch to Opana ER and Endo's other opioids. Far too often Endo's compliance employees yielded to the marketing department at Endo.

287. Endo always knew it had to differentiate itself from Purdue, the market leader, in advertising for Opana ER. In a multi-year brand strategy plan developed in 2006, the year of Opana ER's launch, Endo stated that its "#1 Key Issue" was "OPANA ER may be seen as a me-too [drug], limiting clinical adoption and patient access" and listed as a Strategic Imperative to "[d]ifferentiate OPANA ER based on durability of efficacy and dosing advantage[.]"[314]



Key Issues and Strategic Imperatives

NEW OPANA ER (oxymorphone HCl) Extended-release tablets

	Key Issue	Strategic Imperative
#1	OPANA ER may be seen as a me-too, limiting clinician adoption and patient access	Differentiate OPANA ER based on durability of efficacy and dosing advantages

288. Endo continued to make misleading comparative claims throughout the time that Opana ER was on the market from 2006 until 2017. In a 2008–2012 Opana Brand Tactical Plan dated June 29, 2007, Endo stated as part of "Key Issue #1 Need for continued differentiation of OPANA ER with clinicians and payers[,]" that Endo had an opportunity to "[b]egin to positively position OPANA ER vs. potential competitors."[315]

289. In an Opana Brand Strategy Plan for 2009, Endo stated its intention to use its National Sales Meeting (NSM) to train its sales representatives on competitive messaging with an objective to "[i]ncrease selling confidence among sales force by providing appropriate

[314] ENDO-CHI_LIT-00545916 (slide 22 of 65).

[315] ENDO-CHI_LIT-00541024.

messaging for the key competitors" and to provide "[k]ey OPANA ER selling messages for each competitor."[316]

290. In a separate national sales training document, Endo stated:

> Let's continue by taking a look at the specific details provided by the products' prescribing information *that you can use to differentiate OPANA® from its competitors*. . . . At the end of each table, the Relevance section provides a practical summary of *how the specific features of each product may influence its clinical use, provide an advantage or identify a limitation of a product*[.]

While Endo stated "competitor knowledge information cannot be used for direct head-to-head comparison of treatment efficacy or safety of one product over another[,]"[317] this rule was honored more often in its breach by Endo's Marketing Department and sales representatives.

291. Likewise, in 2010, Endo's Senior Product Manager for the Opana Brand stated that he sought to "[d]ifferentiate OPANA® ER as a less complex treatment option for managing

316 ENDO-CHI_LIT-00546435 (slide 40 of 86).

317 ENDO-OR-CID-00782425, -443 (emphasis added).

moderate to severe chronic low back (cLBP) and OA pain patients" and that "[f]ailure to adequately differentiate OPANA ER will limit the brand's growth in 2010 vs. existing and new competitors in the marketplace."[318]

292. Endo's action plan for the first quarter of 2011 was for its sales force to "[f]ocus on competitive selling."[319]

293. Endo continued to seek to differentiate itself from its competitors. For example, in a 2013 and 2014 sales training on promotional resources available to the Opana ER sales force, Endo stated for its "Opana® ER with INTAC® Campaign: Introduction:"

> Why new positioning and a new campaign? *There is an opportunity to separate Opana® ER with INTAC® from the competition by making an emotional appeal along with product attributes*. By delivering a campaign that is focused *and differentiating*, we aim to have HCPs question their current practices and prescribe Opana® ER with INTAC® for appropriate patients.[320]

294. Endo utilized its sales representatives as a key way to differentiate Opana ER from its competitors. They were incentivized based on how many prescriptions were written in their territories, though Endo's sales compensation formulas varied based on the marketing campaign. And with limited policing of claims or compliance, Endo sales representatives had the financial incentive to differentiate Opana ER from its competitors despite knowing that the company had no rigorous head-to-head studies.

295. Endo ensured that its sales representatives were well-trained and tested on attributes of competing products.[321] Endo required its sales representatives, including those in Tennessee,

---

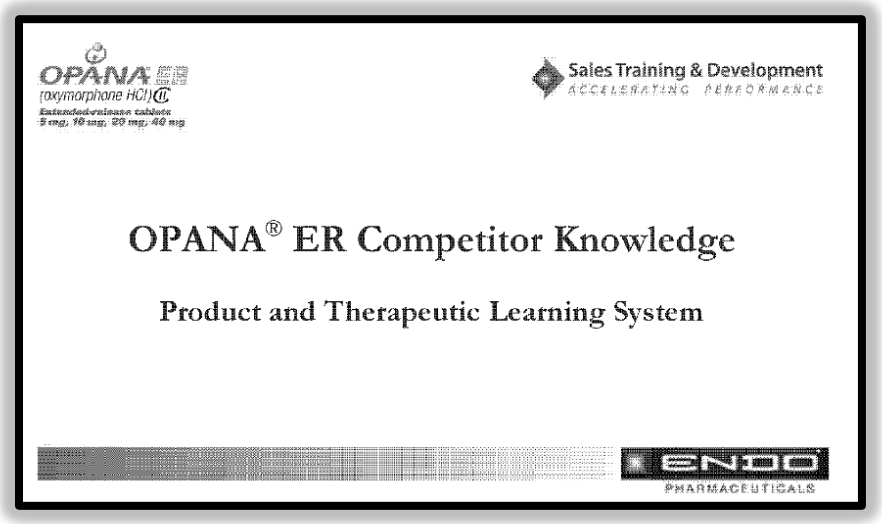
318 ENDO-CHI_LIT-00546621 (slide 3 of 41).

319 ENDO-OR-CID-00633679 (slide 20 of 54).

320 ENDO-CHI_LIT-00550043 (emphasis added); ENDO-CHI_LIT-00556069.

321 ENDO-OR-CID-00782384, -471.

to know extensive details about Opana ER's marketplace competitors as shown by the excerpt below of a *111-page* training manual.



Opana ER v. OxyContin

296. Throughout Opana ER's product life, Endo sought to distinguish it from OxyContin specifically.[322] Endo "hyper targeted" some of the highest OxyContin prescribers in Tennessee and instructed its sales representatives to "[t]ake business from OxyContin where we have good access" with these prescribers.[323]

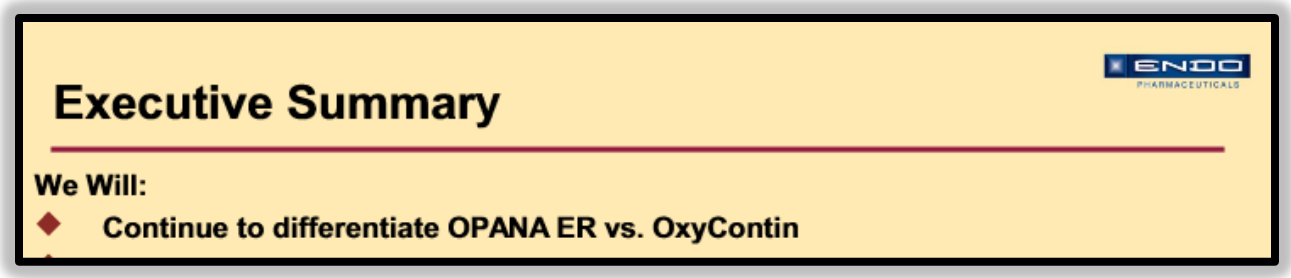
297. In 2007, Endo's marketing department recognized that "differentiat[ing] OPANA ER vs. OxyContin" was a "critical success factor"[324] and stated that it would "[c]ontinue to differentiate Opana ER vs. Oxycontin" as part of its strategic plan.[325]

322 *See, e.g.*, ENDO-OR-CID-00343598 (slides 24, 28, 38 of 74); ENDO-CHI_LIT-556197 (slide 22 of 38).

323 ENDO-OR-CID-00963215 (slide 1 of 2); *see also*, ENDO-CHI_LIT-556197 (slide 26 of 38).

324 ENDO-CHI_LIT-00541043.

325 ENDO-CHI_LIT-00545558 (slide 2 of 48).



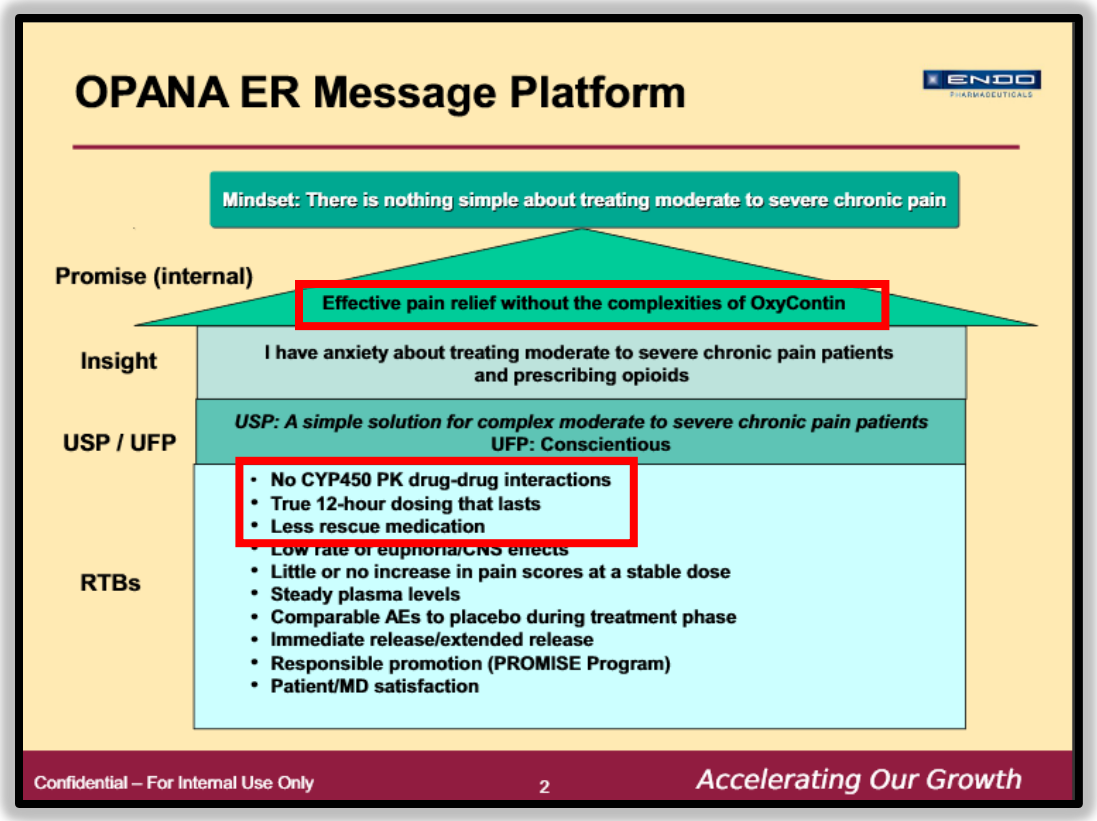
298. In another 2007 document, Endo again identified its ability to "Differentiate OPANA ER vs. OxyContin" as a "Critical Success Factor" and reiterated that one of its primary marketing objectives was to "[c]ontinue to *differentiate* OPANA ER based on its *durable efficacy and dosing advantages*." [326]

299. Endo selected "Effective pain relief without the complexities of OxyContin" as the central promise of Endo's "OPANA ER Message Platform." Among the key reasons to buy (RTB), Endo identified the following, among other things, as claims that would provide an entry point for Endo to compare Opana ER with OxyContin:

- No CYP450 PK drug-drug interactions
- True 12-hour dosing that lasts
- Less rescue medication
- Low rate of euphoria/CNS effects
- Comparable adverse events to placebo during treatment phase.[327]

[326] ENDO-CHI_LIT-00541043, -061, -062 (emphasis added).

[327] ENDO-CHI_LIT-00545559 (slides 2-3); *see also*, ENDO-CHI_LIT-00547048; ENDO-CHI_LIT-00547838 (slide 9 of 20); ENDO-CHI_LIT-00547715 (slide 9 of 18).



300. Endo advanced the "internal" promise externally and implemented it in actual sales calls. Endo training documents taught sales representatives to position Opana ER as easier to manage than OxyContin and requiring fewer rescue medications.[328] In sales calls, Endo positioned Opana ER as safer than OxyContin and represented that it had fewer drug interactions and required less rescue medication.[329]

301. Endo's sales representatives made the claim of "no known CYP450 drug/drug interactions at clinically relevant doses" a "primary selling message for Opana ER"[330] and used the message as an entry point to make superiority claims of Opana ER over OxyContin.

---

328 *See* ENDO-OR-CID-00130647 (slide 85 of 151); *see also*, ENDO-CHI_LIT-00545558 (slide 26 of 48); ENDO-CHI_LIT-00547715; ENDO-OR-CID-00782393, -422.

329 ENDO-OR-CID-00459065 (Opana ER tab).

330 ENDO-OR-CID-00431119; ENDO-OR-CID-00782488; ENDO-OR-CID-00782405, -445; ENDO-OR-CID-00782443.

302. Endo also touted that Opana ER had more "durable" and effective pain relief than OxyContin. Endo even ran Opana ER advertisements that referred to "real" 12-hour dosing and "uniquely engineered for true 12-hour dosing that lasts" as an entry point to make comparative claims about OxyContin, which had the widespread reputation among providers of not lasting for 12 hours.[331]

303. Endo made this 12-hour dosing message a core comparative claim in sales calls. In internal documents, Endo had evidence that:

> *77% of HCP's recalled on an aided basis "true every 12 hour dosing" as the primary message of the OPANA ER sales rep detail.*[332]

304. Endo knew through audits of sales calls that its sales representatives made comparative claims which amplified many of its other deceptive safety, efficacy, and benefit claims. As illustrative examples, Endo knew in 2007 that its sales representatives:

- said Opana ER has a "steadier release of the medication than most of the other medications out on the market[;]"[333]
- made "comparisons with other medications including OxyContin and generic morphine sulfate[;]"[334]
- said Opana ER "has less side effects, including nausea[;]"[335]
- said Opana ER had "less side effect profile[;]"[336]
- said that Opana ER provided "[b]etter control of pain, less risk of abuse[;]"[337]

---

331 ENDO-CHI_LIT-00541049.

332 ENDO-OR-CID-01228484 (emphasis added).

333 ENDO-CHI_LIT-00548027.

334 ENDO-CHI_LIT-00548027.

335 ENDO-CHI_LIT-00548027.

336 ENDO-CHI_LIT-00548039.

337 ENDO-CHI_LIT-00548028.

- said that Opana ER is a "new long acting pain medication that doesn't have the negative press of OxyContin and is an effective agent, something to try for people not controlled on their current regimen[;]"[338]
- said that Opana ER had "less side effects and easier to take medication than OxyContin[;]"[339]
- said that Opana ER had "less abuse potential[;]"[340]
- said that Opana ER "is safer than OxyContin and has less hepatic metabolism problems[;]"[341]
- said that Opana ER "was supposed to be more effective[;]"[342]
- said "maybe less habituation or euphoria when taking Opana and therefore may be able to discontinue it easier[;]"[343]
- said "Opana ER was compared to OxyContin and felt to be much safer, better tolerated, less peaks and valleys, and pain control[;]"[344]
- said "There are no peaks or immediate peaks such as seen with OxyContin so that patients don't get high and there's a steady level which is what is needed for chronic pain[;]"[345]
- said that patients on Opana ER "tend to feel more energetic on this particular formulation as opposed to perhaps competing long-acting morphine products[;]"[346]and
- said that Opana ER had "[l]ess euphoria and maybe less addictive potential[.]"[347]

305. Endo also continued to make unsubstantiated comparative claims about OxyContin while both its original and reformulated versions of Opana ER were on the market. In June 2012, part of Endo's "Opana ER Action Plan" was to focus on converting OxyContin and MS Contin

[338] ENDO-CHI_LIT-00548029.
[339] ENDO-CHI_LIT-00548029.
[340] ENDO-CHI_LIT-00548030.
[341] ENDO-CHI_LIT-00548034.
[342] ENDO-CHI_LIT-00548036.
[343] ENDO-CHI_LIT-00548038.
[344] ENDO-CHI_LIT-00548039.
[345] ENDO-CHI_LIT-00548398.
[346] ENDO-CHI_LIT-00548041.
[347] ENDO-CHI_LIT-00548045.

prescribers to the reformulated Opana ER.[348] Endo carried on this strategy to encourage health care providers to switch from OxyContin or MS Contin in 2013[349] and thereafter.

Reformulated Opana ER v. Generic Opana ER Old Formulation

306. In addition to misleading OxyContin comparisons, Endo also emphasized deceptive comparative claims about the abuse deterrence properties of its reformulated Opana ER compared to the original version.

307. Endo misrepresented the abuse-deterring extent of its reformulated Opana ER compared with generics that were bio-equivalent to its original formulation.

308. Opana ER was reformulated to supposedly be crush-resistant and thus more difficult to abuse, the idea being that if it were difficult to crush the pills then they were less likely to be snorted or injected intravenously. Endo's own studies showed that the so-called abuse deterrent properties of the reformulation were either nonexistent or overstated: the pills could be easily cut (which would result in dose-dumping if ingested), were as prone to or more prone to intravenous abuse than the original, and had minimal improvement concerning crushing over the old formulation. Endo also had evidence that the rates of intravenous abuse of the reformulated Opana ER exceeded the rates of snorting of the original formulation.[350] Yet, Endo repeatedly overstated the abuse deterrent capabilities of its reformulated Opana ER compared with generic versions of the old formulation.

309. Endo instructed all of its sales representatives to "communicate prioritized messages in all HCP [health care provider] discussions," including that:

- Opana ER with INTAC is the only oxymorphone designed to be crush-resistant[;]

348 ENDO-OR-CID-01311385.

349 ENDO-OR-CID-00131019 (Opana ER tab).

350 ENDO-OPIOID_MDL-4940040.

- The generics are not designed to be crush-resistant and are not therapeutically equivalent to Opana ER with INTAC[;]
- The original formulation of Opana ER was discontinued by Endo because the original formulation was not designed to be crush resistant[; and]
- The only way for your patients to receive oxymorphone ER in a formulation designed to be crush resistant is to prescribe Opana ER with INTAC.[351]

310. Endo widely disseminated its comparative claims about its opioid products and competing products to health care providers and the public in Tennessee.

311. Because the claims involve health and safety, they are material claims upon which reliance is presumed.

312. Endo did not have head-to-head studies establishing that its opioid products were superior to competing products in terms of safety or efficacy. Endo's comparative claims about its opioid products and competing products were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's products were superior to competing products when this was not the case or when it did not have competent and reliable scientific evidence to substantiate such claims at the time they were made.

C. DECEPTIVE BENEFIT CLAIMS

313. In its marketing materials and through its sales representatives, Endo made a series of representations about the benefits and characteristics of its opioid products that were not approved by the FDA and for which it lacked adequate substantiation. Endo did this primarily by representing that its products would improve a patient's function, quality of life, sleep, emotional well-being, work productivity, concentration, or self-esteem. These claims were false, deceptive, and/or unsubstantiated at the time they were made.

[351] ENDO-OR-CID-00243231, -232; ENDO-OR-CID-00243234, -235.

314. The 2016 CDC Guideline concluded after a "systematic review of the best available evidence" by an independent expert panel that no study exists to show opioids are effective for outcomes related to quality of life.[352] Further, powerful narcotics that can kill patients or commit them to a life of addiction or recovery cannot be said to broadly improve a patient's quality of life.

315. While opioids may initially improve function by providing pain relief in the short term, Endo's claim that opioids improve patients' function in the long term is unsubstantiated.

316. The 2016 CDC Guideline also determined that "there is *no good evidence* that opioids improve pain or function with long-term use." The CDC reinforced this throughout the Guideline, finding that: "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later," "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term therapy," and "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."[353]

317. Despite the known lack of evidence, Endo's written marketing materials represented that its opioid products could improve a patient's function.

318. As early as 2004, Endo's opioid promotions made claims that opioids would improve one's function. Endo stated, among other things:

- "Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the rights reasons—to relieve your pain *and improve your function*. You are not addicted[;]"

[352] 2016 CDC Guideline, at 9.

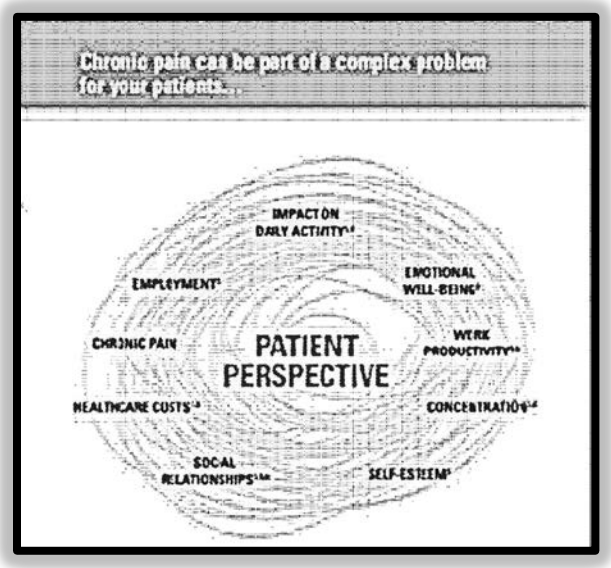
[353] 2016 CDC Guideline, at 12, 15, 18–20.

- "How much and how often should I take my pain medicine? Keep on top of your pain—don't wait until pain becomes severe to take your medicine. Pain is easier to control before it reaches full force. Set a goal with your doctor or nurse for pain relief that *makes it easy for you to sleep at night and to do your daily activities*[;]"[354]

- "Set a goal for pain relief. *Ask yourself what activities you need to do*, such as getting out of bed, *sleeping*, or walking. Then decide what pain rating will make it easy for you to carry out those activities. Everyone is different, but many people need a pain rating of 3 or less to be able to function well[; and]"

- [An example pain control record that stated] "care for self-perform prescribed exercises." [355]

319. Endo used visual aids claiming that its opioids, such as Opana ER, would help with a patient's overall well-being. In one of its "master visual aids" distributed nationwide for Opana ER, Endo made implicit claims that its opioid products would help patients keep working and improve their daily activities, emotional well-being, work productivity, concentration, and self-esteem.[356]



354 https://perma.cc/QN86-62PK (emphasis added).

355 https://perma.cc/QN86-62PK (emphasis added).

356 ENDO-OR-CID-00782399 (Patient Perspective from the Master Visual Aid).

320. Endo sales representatives used the deceptive benefit claims to promote Opana ER to health care providers. The following are illustrative examples of messages that Endo sales representatives delivered to health care providers during sales calls:

- 24-hour pain relief so patients can function normally[;][357]
- Returns patients more rapidly and more fully to their usual activities of daily life and their ability to function therein[;][358]
- [I]mprovement in physical and social functioning as well as sleep and true 12-hour pain control to keep patients active and return to their work and daily activities[;][359]
- Safety and improvement in activities of daily living and sleep[;][360]
- 12 hour drug, improves sleep for the patient[; and][361]
- Studies with dental pain, low back pain, and other types of pain have shown that Opana has proven efficacy as far as reduction in pain and improvement in quality of life in head to head comparisons[.][362]

321. Endo also instructed its sales representatives to tell health care providers that opioids would improve patients' ability to function, allowing them to return to work and increase physical activity. For example, an Endo sales brochure with the tagline "HE NEEDS RELIEF[,] YOU NEED A SOLUTION," featured a fictional construction worker named Ray "who needs to work to support his family" and "still experiences significant pain at the end of each workday." The brochure ends by stating "Ray needs a chronic pain management plan *that works*—for you both."[363]

---

357 ENDO-CHI_LIT-00548301.

358 ENDO-CHI_LIT-00548367.

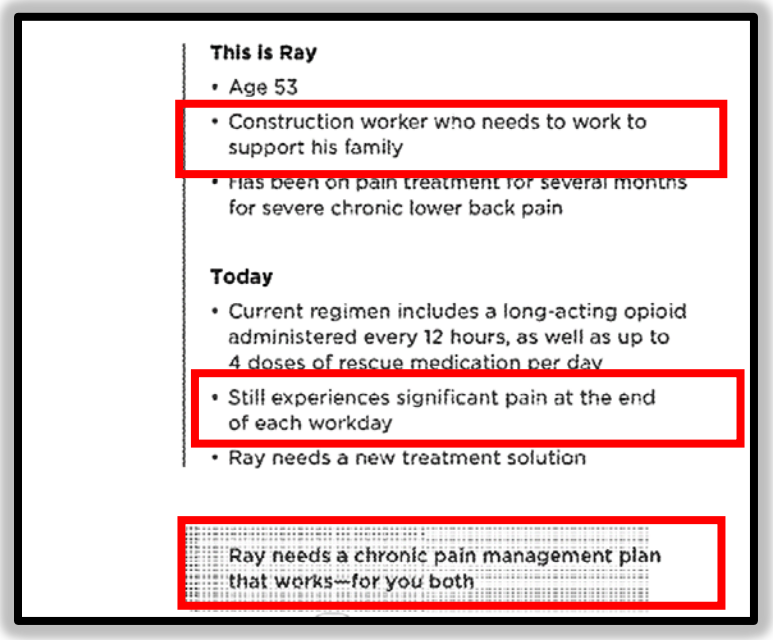
359 ENDO-CHI_LIT-00548306.

360 ENDO-CHI_LIT-00548398.

361 ENDO-CHI_LIT-00548034.

362 ENDO-CHI_LIT-00548163.

363 ENT000051687 (emphasis added).



322. Another Endo advertisement featured a fictional chef named Janice and implied that Opana ER would improve her ability to function at work.[364]

[364] ENDO-OR-CID-00005512.

323. Endo widely disseminated benefit claims about its opioid products, including claims that the products improved function, quality of life, sleep, emotional well-being, work productivity, concentration, or self-esteem, to health care providers and the public in Tennessee.

324. Because the claims involve health and safety, they are material and reliance is presumed.

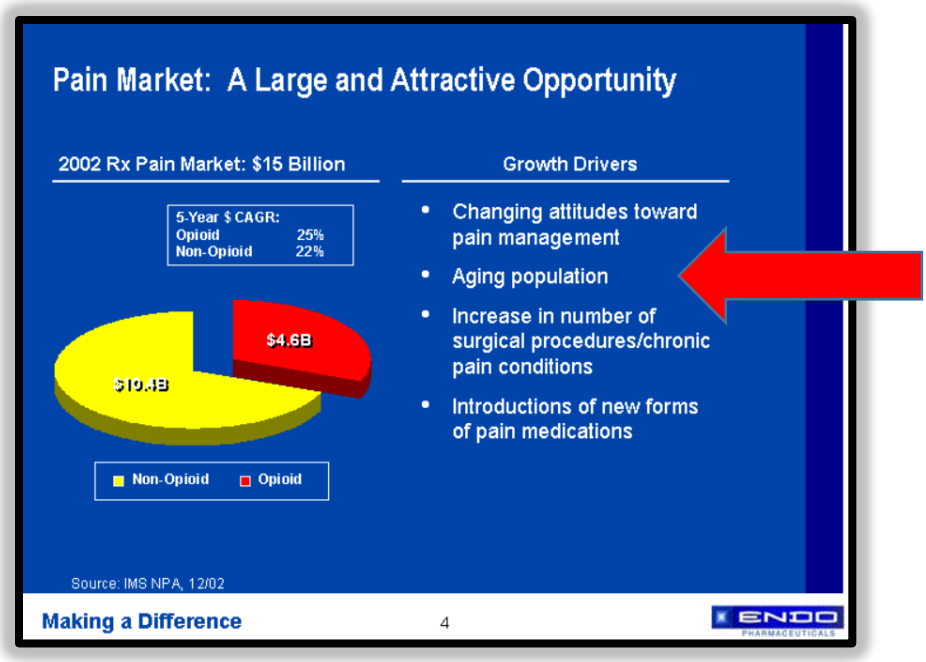
325. Endo's benefit claims about its opioid products, including that they could improve one's function, quality of life, sleep, emotional well-being, work productivity, concentration, or self-esteem, were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products provided such benefits when this is not the case or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

D. DECEPTIVE CLAIMS ABOUT OPIOID USE IN THE ELDERLY

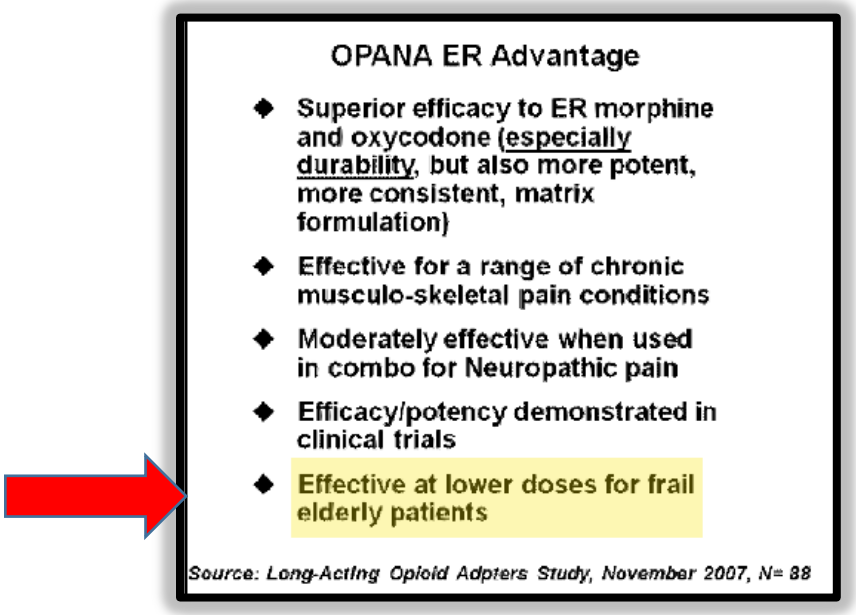
326. Endo misrepresented the safety of its opioids in the treatment of elderly patients through a series of affirmative statements and material omissions. Endo specifically targeted the elderly with marketing claims that Opana ER could help improve osteoarthritis, a condition predominantly associated with elderly patients, and that Opana ER had fewer drug interactions. Endo used these deceptive claims to make its opioids a seemingly more attractive option for health care providers with elderly patients since many were already on other prescription drugs. Endo's promotion of these claims failed to disclose the increased risk of respiratory depression, death, and other serious health risks for elderly persons taking opioids.

327. Early on, Endo recognized the profitability of marketing opioids to elderly populations. During a 2003 presentation at a healthcare investor conference that previewed the entry of Opana ER into the marketplace, Endo identified "Aging population" as a "growth driver" for the pain market, which it described as a "Large and Attractive Opportunity."[365]

[365] Making a Difference Powerpoint, CIBC WORLD MARKETS 14TH ANNUAL HEALTHCARE CONFERENCE, ENDO PHARMACEUTICALS INC., (Nov. 12, 2003), *available at* https://www.sec.gov/Archives/edgar/data/1100962/000095012303012517/y91613exv99w1.htm (stating "Market Need Addressed: . . . We believe that it will provide equivalent analgesia with only half the milligram dosage of OxyContin") (slide 4 of 22).



328. In a 2008 internal marketing document which studied health care providers who prescribe long-acting opioids, Endo noted that one "advantage" of Opana ER was that it was purportedly "[e]ffective at lower doses for frail elderly patients."[366]



366 ENDO-OR-CID-00130753 (emphasis added in image).

329. Endo's opioid marketing did in fact focus on "elderly patients taking multiple [medications] and those suffering from [osteoarthritis.]"[367]

330. The intentional, unqualified targeting of the elderly was especially egregious for Opana ER because, as Endo knew, the drug was supposed to be used with caution in elderly patients as a result of the steady-state concentrations of oxymorphone being 40% higher in elderly patients than in younger patients[368] and the greater frequency of severe adverse events observed in Opana ER patients 65 years and older.[369]

331. Nevertheless, Endo relentlessly pursued seniors for its opioids. Endo established a "[s]trategic imperative" to "[i]ncrease the profitability through most valuable customer segments" which included "patient share in . . . [osteoarthritis]."[370] Elsewhere, Endo stated its intention to "[e]xploit new clinical opportunities for Opana ER use – Develop NPP approach to impact [long term care] and hospital segments."[371]

332. Endo trained its sales representatives, including those in Tennessee, to promote Opana ER for use in osteoarthritic patients. The claim was so prevalent that in 2010 Endo provided "[O]steoarthritis Disease State conversation" as a default drop-down message for its sales representatives to select when filling out their call notes about visits with providers.[372]

333. In another example from 2010, Endo unveiled the "Innovate Lead" campaign at its annual Opana ER National Meeting Workshop. The "Innovate Lead" campaign taught and tested Endo's sales representatives about marketing Opana ER as an osteoarthritis pain treatment without

---

367 *See, e.g.*, ENDO-OR-CID-00179309; *see also*, ENDO-CHI_LIT-00546650 (slides 2, 12-15, of 26).

368 ENDO-OR-CID-00668533.

369 ENDO-CHI_LIT-00545453.

370 ENDO-OR-CID-00160777.

371 ENDO-OR-CID-633679 (slide 19 of 54).

372 ENDO-OR-CID-00459065 (Opana ER tab).

reference to the increased risks of respiratory depression and other health risks from use of Opana ER in the elderly.[373] Endo's sales representatives represented that Opana ER could help treat osteoarthritic pain without clearly and conspicuously disclosing the increased risk of respiratory depression and other health risks associated with use by the elderly.

334. In the 2007 sales call audits, Endo even specifically tracked what sales representatives said, "regarding Effective and safe [use] in the elderly."[374]

335. For example, a health care provider reported that an Endo sales representative stated during a sales call that "[a]n important consideration when dealing with older people in chronic pain is drug-drug interaction with polypharmacy but the sales rep ensured that this CYP [Cytochrome P450] enzyme will not be induced or inhibitive [sic] by Opana ER"[375] without disclosing the increased risk of respiratory depression, death, and other serious health risks.

336. As part of its marketing for Opana ER, Endo also trained its paid speakers that:

- "Under prescribing of analgesics to the elderly contributes to poor chronic pain management."[376]
- "Drug-drug interactions are of great concern, as polypharmacy is common in the elderly."[377]
- "In routine practice settings, more than 40% of patients with chronic pain do not achieve adequate relief."[378]

[373] ENT000098729.

[374] ENDO-CHI_LIT-00548107.

[375] ENDO-CHI_LIT-00548066.

[376] ENDO-OR-CID-01286267.

[377] ENDO-OR-CID-01286270.

[378] ENDO-OR-CID-01286275.

337. Endo's marketing materials also claimed that Opana ER could be used to treat osteoarthritis without clearly and conspicuously disclosing the increased risk of respiratory depression and other health risks in the elderly.

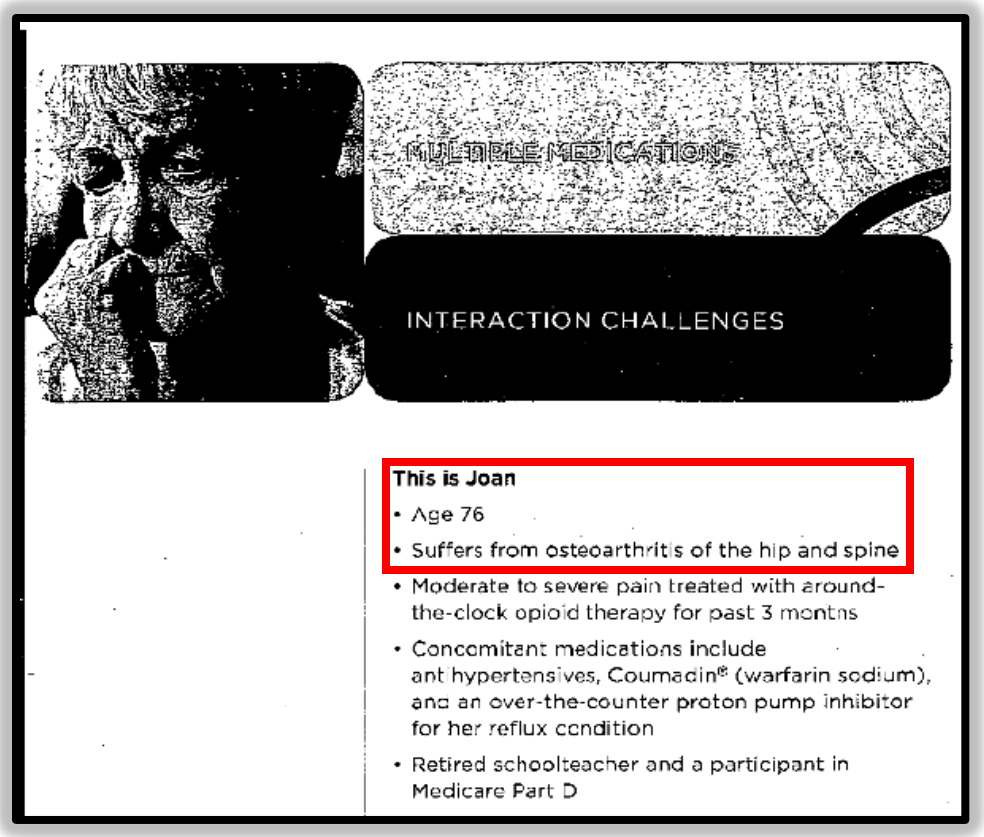
338. For example, Endo debuted an Opana ER brochure in April 2011[379] that featured a fictitious patient named "Joan" who was a 76-year-old retired school teacher with osteoarthritis in her hip and spine. The ad failed to clearly and conspicuously disclose the increased risk of respiratory depression and other health risks in the elderly, despite also stating "[a]fter 3 months of increasing doses of her opioid, Joan's pain [was] not well controlled."[380]

339. Endo's brochure, which originally ran under the code OP-01065, also emphasized Opana ER's purported safety when taken with other prescription medications. It depicted "Joan," a 76-year-old woman, as taking multiple other prescription medications, including an anti-depressant and blood pressure medications, and stated, "[OPANA® ER HAS] NO KNOWN CYP450 PK DRUG-DRUG INTERACTIONS AT CLINICALLY RELEVANT DOSES."[381]

[379] ENDO-OR-CID-00035398; *see* ENDO-OR-CID-00103064; ENDO-OR-CID-00081734; ENDO-OR-CID-00081597.

[380] ENT000056795; ENDO-OR-CID-00183261; ENDO-OR-CID-00124280.

[381] ENT000056795 (excerpted above); ENT000056800.



340. Endo also used a similar fictional 68-year-old patient named "Stella" on its website, www.opana.com, where it said that "Stella needs improved pain control while managing the risk of interactions with her other medications"[382] and treatment for osteoarthritis[383] without clearly and conspicuously disclosing the increased risk of respiratory depression and other health risks in the elderly.

341. In addition, Endo strategically placed its ads in journals that would appeal to health care providers with large elderly patient populations. For example, in a 2010 Oxymorphone Franchise Tactical Plan prepared by Endo's Senior Product Manager for the Opana Brand, Endo

[382] ENDO-CHI_LIT-00537622 (Code OP-0416B).

[383] ENDO-CHI_LIT-00537622.

stated that one of its target audiences for the journal ad campaign advertising Opana ER for lower back pain and osteoarthritis was geriatric journals.[384]

342. Endo misrepresented the safety of its products in the elderly by (1) omitting the material fact that there is a greater risk of certain side effects, such as respiratory depression and falls, from the use of Opana ER in elderly patients, and (2) omitting the material fact that low-dose starts of Opana ER in elderly patients most often lead to higher doses of Opana ER, which increases a number of risks.

343. Endo's claims about use of its opioid products in the elderly were widely-disseminated to health care providers and the public in Tennessee without clear and conspicuous disclosure of the increased risk of respiratory depression and other health risks in the elderly.

344. Because the claims involve health and safety, they are material and reliance is presumed.

345. Endo's claims about the beneficial use of its opioid products in the elderly without clear and conspicuous disclosure of respiratory depression and other health risks were false, misleading, and deceptive because they led health care providers and the public to believe that Endo's opioid products were safer for the elderly than they really were or when such claims were not supported by competent and reliable scientific evidence at the time they were made.

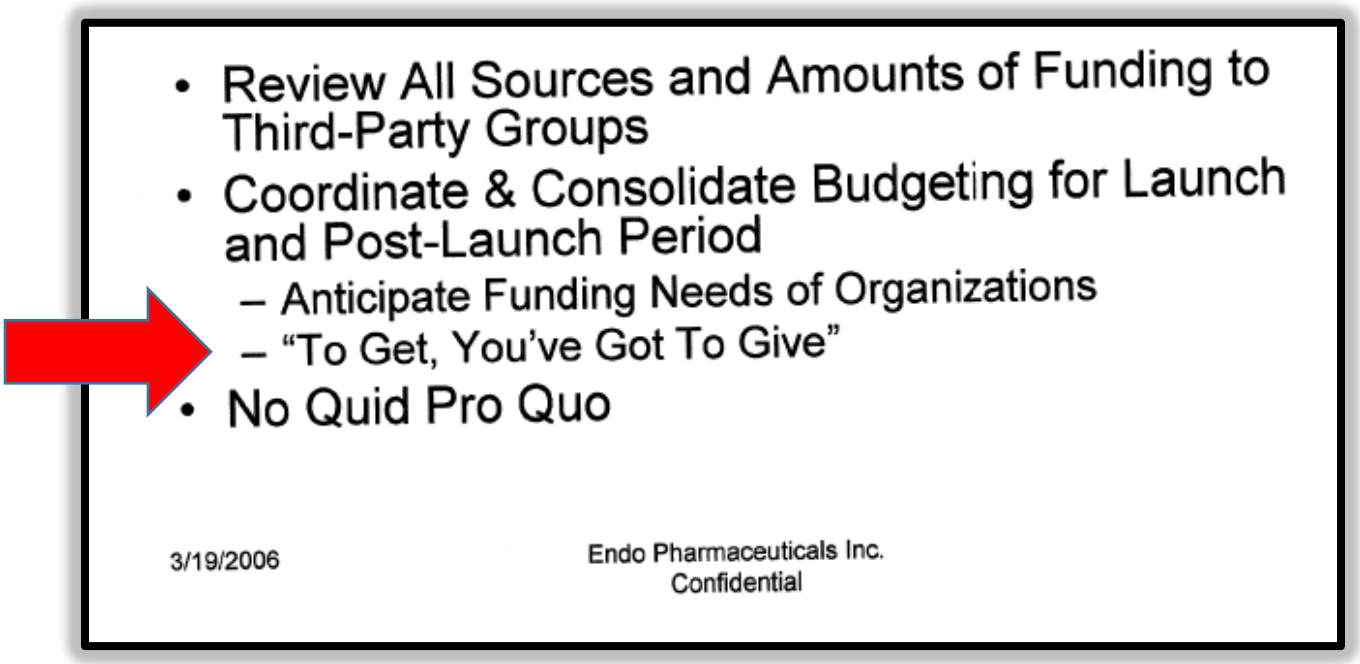
E. OMISSIONS OF MATERIAL CONNECTIONS

346. In marketing for its own opioid products, Endo routinely referred to positions and publications of third-party pain advocacy groups to support Endo's position about a health care issue without clearly and conspicuously disclosing the material fact that Endo was a substantial financial contributor to the third-party groups.

[384] ENDO-CHI_LIT-00546621 (slide 20 of 41).

347. This material omission had the effect of making the third-party pain advocacy groups' positions or recommendations appear more credible or more neutral than they otherwise would have had the material fact of Endo's substantial monetary contributions been disclosed.

348. Endo's consultant recommended to Endo that it should "Review All Sources and Amounts of Funding to Third-Party Groups" and "Anticipate [the] Funding Needs of Organizations" because "*To Get, You've Got to Give*."[385]



349. Endo incorporated publications from these third-party pain advocacy groups into the company's marketing for its branded opioid products like Opana ER. One of the most significant types of third-party publications that Endo touted in its marketing were treatment guidelines, which the CDC has recognized can "change prescribing practices."[386]

[385] ENDO-CHI_LIT-00543566 (emphasis added).

[386] 2016 CDC Guideline at 2.

350. Endo knew how influential treatment guidelines could be for providers and used "Appropriate Use Guidelines for P[rimary] C[are] P[hysician]s" and the OPANA ER Tool Kit (which contained third-party dosing guidelines) as a "Key Initiative" to help "[e]ntrench OPANA ER as a preferred therapy based on durable efficacy and unique set of dosing advantages."[387]

351. Endo was a substantial contributor to the American Pain Foundation (APF), the self-described "largest advocacy organization for people with pain" in the country. APF abruptly disbanded in May 2012 shortly after receiving a letter from the U.S. Senate Finance Committee, which was investigating the link between opioid manufacturers and pain advocacy groups. As shown by an investigation by ProPublica, APF's guidelines downplayed the risks associated with opioids while exaggerating the benefits. As the investigation also found, in 2010, APF received 90% of its $5,000,000 in funding from the drug and medical-device industry,[388] including Endo which gave APF over $1,000,000 and was by far its single largest donor.[389] Endo contributed *53%* of APF's income.[390] Between 1999 and 2012, Endo gave APF $5,941,671.40.[391]

352. Endo also contributed financially to the American Geriatric Society (AGS), a trade association of health care providers for the elderly. Endo gave AGS $341,785 between 2000 and 2011.[392] In sales calls, Endo sales representatives distributed the AGS Guidelines for opioid treatment[393] without disclosing Endo's financial relationship to the group.

---

387 ENDO-CHI_LIT-00541053; - 56, -57.

388 Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012), *available at* https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

389 Am. Pain Found., *Annual Report* (2010), https://archive.org/details/277604-apf-2010-annual-report/page/n19.

390 https://www.documentcloud.org/documents/277604-apf-2010-annual-report (18 of 28).

391 ENDO#6.1.

392 ENDO#6.1.

393 ENDO-CHI_LIT-00546625 (spreadsheet row 33 listing $70,000 budget line-item for AGS Guidelines Reprint Carrier).

353. Endo used the AGS Guidelines in branded marketing for its opioids, including Opana ER. Following focus groups with health care providers in 2009, Endo identified "[a] clear opportunity for messaging to older patients based on AGS guidelines for opioid use[.]"[394] Endo also referenced the AGS Guidelines on Opioid Use in Elderly Patients in its own marketing materials without disclosing its financial connection to the group.[395]

354. In addition, Endo contributed financially to the American Academy of Pain Medicine (AAPM) and the American Pain Society (APS). Endo even described its attendance at the AAPM meeting as a "promotional activity."[396] Between 1998 and 2012, Endo gave APS $4,468,253.10.[397] Between 1999 and 2012, Endo gave AAPM $1,311,940.00.[398] In 2009, the AAPM and the APS jointly published Guidelines for opioid treatment. Endo extensively trained its sales representatives to discuss the AAPM/APS Guidelines in sales calls with providers[399] and disseminated them without disclosing Endo's financial connections to the groups. Similarly, Endo used the APS and AAPM guidelines in speaker programs that were part of the company's Opana ER marketing without disclosing Endo's financial connections to the groups.[400]

355. Overall, Endo paid these seemingly independent third-party "advocacy" groups $12,063,649.50.

356. Endo widely disseminated and promoted guidelines and educational materials to health care providers and the public in Tennessee published by third-party advocacy groups that it

394 ENDO-OR-CID-00136446.

395 ENDO-OR-CID-00094095.

396 ENDO-CHI_LIT-547149 (slide 12 of 13).

397 ENDO#6.1.

398 ENDO#6.1.

399 ENT000094378; ENDO-CHI_LIT-00546873; *see* ENDO-CHI_LIT-00546240; ENT000090342.

400 ENDO-OR-CID-01286277.

substantially funded without clear and conspicuous disclosure of Endo's financial connection to the third-party advocacy groups.

357. Because the claims involve express statements and a substantial monetary contribution, they are material and reliance is presumed.

358. Endo's use of guidelines and educational materials from third-party advocacy groups in marketing for its opioid products without clear and conspicuous disclosure of its monetary contribution to the groups was false, misleading, and deceptive because the practice led health care providers and the public to believe that the information or advice contained in the guidelines was neutral and unbiased when this was not the case.

F. ENDO IS SUBSTANTIALLY RESPONSIBLE FOR THE OPIOID EPIDEMIC IN TENNESSEE

359. The United States has approximately 4.4% of the world's population, but accounts for the vast majority of opioids consumed globally, including oxymorphone, which is the concentrated active ingredient in Opana ER.

360. This imbalance occurs not because Americans or Tennesseans experience pain at higher rates than their global or national peers or have greater access to healthcare. Rather, it is due in large part to "aggressive marketing by pharmaceutical companies," as recognized by the Director to the National Institute on Drug Abuse within the National Institutes of Health in a 2014 report to the U.S. Senate.[401]

361. Within the United States, Tennessee accounts for disproportionately high rates of per capita opioid consumption generally, and oxymorphone consumption specifically. Tennessee

[401] Nora Volkow, M.D., *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, NATIONAL INSTITUTE ON DRUG ABUSE (May 14, 2014) *available at* https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

has likely suffered more devastation because of Endo's aggressive and deceptive marketing of Opana ER than any other state in the country.

362. Tennessee still had the third highest prescription rate in the country in 2017[402] and the CDC measured it as having among the most opioids prescribed per person in the country.[403] As known to Endo, Tennessee has also continued to have some of the highest rates of prescription opioid abuse in the nation,[404] particularly in the eastern part of the state. In 2017, the nationwide rate of drug-related deaths was 21.7 per 100,000 people.[405] Tennessee's rate of drug-related deaths was higher than the national average at 26.6,[406] and within Tennessee, some Eastern counties had almost triple the national average, like Knox County at 68.4 and Anderson County at 60.3.[407] Oxymorphone has been among the most frequently identified drugs in drug-related deaths in Tennessee.[408]

363. A substantial portion of Tennessee's prescriptions and high MME levels came from Opana ER—especially high dose (20 mg or higher). Between 2007 and 2014 in Tennessee, the following amounts of Opana ER were prescribed:

- 1,817,154,028 MMEs, with 1,573,803,928 or *87%* of that being high dose,
- 25,779,741 tablets, with 17,797,992 or *69%* of that being high dose, and

---

402 https://www.cdc.gov/drugoverdose/maps/rxstate2017.html.

403 https://www.cdc.gov/vitalsigns/opioids/infographic.html.

404 *See* ENDO-OR-CID-00372546.

405 *Drug Overdose Deaths*, U.S. CENTERS FOR DISEASE CONTROL, *available at* https://www.cdc.gov/drugoverdose/data/statedeaths.html.

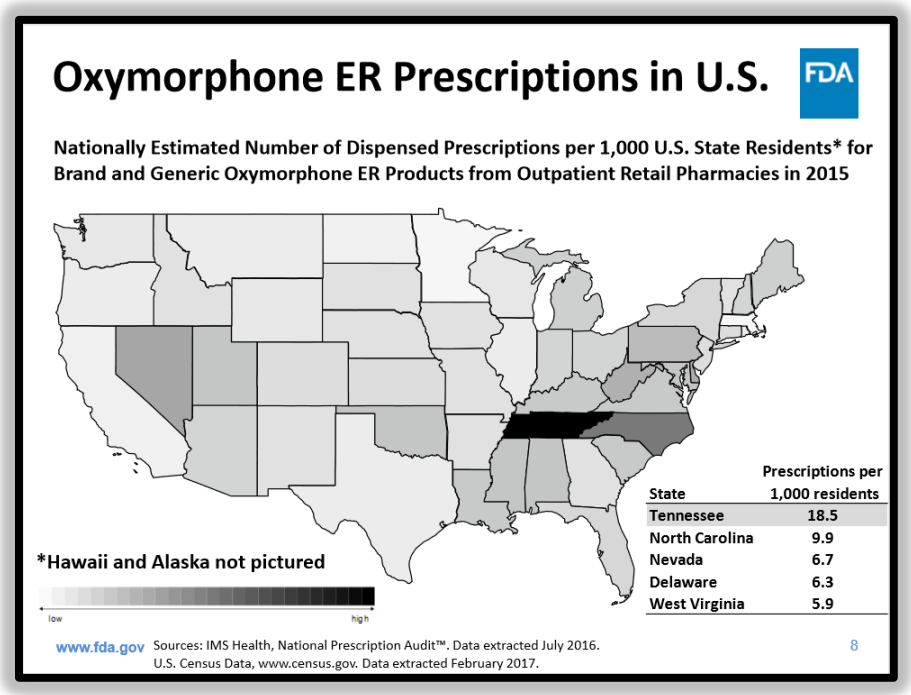
406 *Drug Overdose Deaths*, U.S. CENTERS FOR DISEASE CONTROL, *available at* https://www.cdc.gov/drugoverdose/data/statedeaths.html.

407 *Knox County Regional Forensic Center Drug-related Death Report*, KNOX COUNTY REGIONAL FORENSIC CENTER, *available at* https://knoxcounty.org/rfc/pdfs/KCRFC_DRD_Report_2017.pdf (slide 30 of 111).

408 *Drug-related Deaths in Knox, Anderson Counties Increased More than 41 Percent from 2016*-17, KNOXVILLE NEWS SENTINEL, *available at* https://www.knoxnews.com/story/news/health/2018/09/12/knoxville-drug-related-deaths-knox-anderson-counties-increase-fentanyl/1277795002/

- 424,536 prescriptions, with 282,970 or *67%* of that being high dose.[409]

364. According to the FDA, Tennessee had by far the highest rates of Opana ER and generic oxymorphone ER prescriptions in the country, nearly double those of the second-highest state. For example, in 2015, 18.5 prescriptions of oxymorphone ER were prescribed per 1,000 residents in Tennessee. North Carolina, the second-highest state, had 9.9 prescriptions per 1,000 residents.[410]

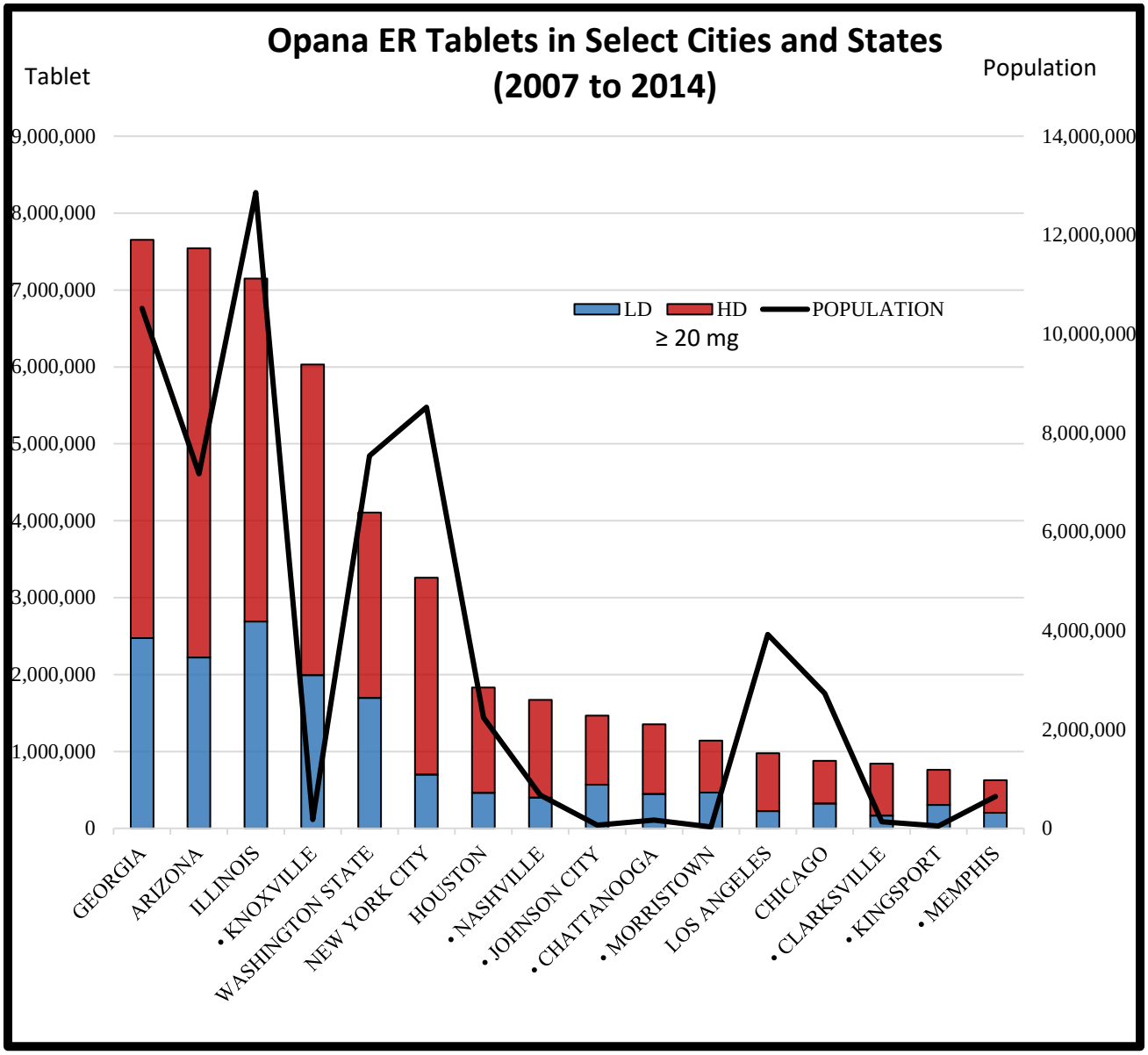


365. Endo's sales calls translated into increased sales of Opana ER tablets in Knoxville, East Tennessee, and Tennessee generally in such mind-boggling numbers that Endo *had* to know that abuse or diversion of its opioids was rampant. As shown by the chart below, between 2007 and 2014, *Endo sold:*

409 ENDO-OR_MASS_CIDS-0000047.

410 https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf (slide 9 of 165).

- 916,513 more Opana ER tablets in Knoxville than it sold in New York City, Los Angeles, and Chicago *combined—cities which collectively have 82 times Knoxville's population*;
- roughly 2,000,000 more Opana ER tablets in Knoxville than the *entire* State of Washington, *which has roughly 42 times Knoxville's population*;
- more Opana ER tablets in Morristown, with a population under 30,000, than Los Angeles, *which has 134 times Morristown's population*.[411]



411 ENDO-OR_MASS_CIDS-0000047.

Location	Population	Low-Dose Opana ER Tablets	High-Dose Opana ER Tablets (≥20 mg)	Total
Georgia	10,519,475	2,473,361	5,179,728	7,653,089
Arizona	7,171,646	2,222,105	5,320,355	7,542,460
Illinois	12,859,995	2,690,290	4,459,705	7,149,995
• Knoxville	178,874	1,991,104	4,039,007	6,030,111
Washington State	7,535,591	1,696,135	2,410,922	4,107,057
New York City	8,521,000	700,645	2,558,386	3,259,031
Houston	2,239,000	462,731	1,367,553	1,830,284
• Nashville	670,314	397,668	1,271,994	1,669,662
Dallas	1,279,000	454,137	1,045,490	1,499,627
• Johnson City	65,196	567,904	898,832	1,466,736
• Chattanooga	167,674	446,947	904,707	1,351,654
• Morristown	29,222	465,400	674,938	1,140,338
Los Angeles	3,923,000	223,184	752,703	975,887
Atlanta	455,589	236,741	690,358	927,099
Chicago	2,727,000	323,743	554,937	878,680
• Clarksville	132,929	165,719	677,428	843,147
• Kingsport	48,205	305,608	457,008	762,616
• Memphis	646,889	201,188	426,012	627,199

366. Among the branded marketers of opioids, Endo was one of the most audacious and effective. Its aggressive and deceptive marketing and other conduct has played a substantial role in creating and prolonging the opioid epidemic in Tennessee. Endo's conduct led to widespread addiction, abuse, diversion, overdoses, deaths, and other negative consequences which forced the State and its political subdivisions to spend significant resources in an ongoing attempt to handle the crisis.

367. Endo's sales calls to health care providers generated more prescriptions for Opana ER and Endo's other opioid products than at providers not visited by Endo. The company knew that more sales calls to the top prescribers of its opioid products led to more prescriptions and that

its return on investment for sales calls to the highest prescribers (known as decile 10 prescribers) was significantly higher than prescribers who wrote fewer Opana ER prescriptions.[412]

368. Endo also pushed health care providers to prescribe higher doses of Opana ER, which have a higher street value than lower doses. The company's disproportionate sales of high-dose Opana ER in Tennessee, especially in late 2010 and thereafter, [413] was a red flag that a substantial portion of its sales were coming from abuse or diversion of Opana ER.

369. Endo knew the consequences of aggressive and deceptive marketing for a controlled substance—and went full-steam ahead anyway for over a decade. Before it launched Opana ER, an opioid twice as potent as OxyContin, in 2006, Endo was aware of the high likelihood of abuse and diversion that would result.[414]

370. Endo knew that among opioids, oxymorphone had some of the highest rates of abuse based on the total number dispensed. For example, in a 2011 internal report based on data from the National Addictions Vigilance Intervention & Prevention Program (NAVIPPRO), a drug abuse surveillance database, Endo knew that:

> [w]hen considering the total number of prescriptions dispensed of a particular opioid compound or drug as the denominator, the opioid compound with the highest rate of abuse during [the second quarter of 2011] was for *any oxymorphone*, followed by fentanyl, oxycodone, and then hydrocodone.[415]

371. Endo was also aware that Tennessee had some of the highest rates of Opana ER abuse in the nation. In the same summary of NAVIPPRO data for the second quarter of 2011, Endo knew:

---

412 ENDO-CHI_LIT-00546435 (slide 22 of 86).

413 https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM547235.pdf (slide 9 of 165).

414 *See, e.g.*, ENDO-CHI_LIT-00543523.

415 ENT000066133 (emphasis added).

> Past 30-day abuse of OPANA ER was reported in 18 of the 34 states that contributed data with the greatest number from patients in substance abuse treatment in West Virginia, Pennsylvania, New York, and *Tennessee*.[416]

372. Endo knew for years that Tennessee continued to have much higher abuse rates of Opana ER. Through a 2016 NAVIPPRO report, Endo was aware that:

> [a]nalyses of Tennessee separately show nearly *10 times* the magnitude of past 30-day abuse prevalence of both [the reformulated Opana ER] and generic oxymorphone ER in the post-period than in other, non-Tennessee states.[417]

373. Despite this ongoing knowledge over a period of many years that Tennessee had very high rates of abuse of Opana ER, Endo continued to instruct its sales representatives to visit, and continue to visit, some of the most notorious pill mills in Tennessee, as well as other practices where there were red flags for abuse and diversion of opioids including Opana ER.[418]

374. Endo gave "A" letter grades to providers who wrote high numbers of prescriptions of Opana ER and other opioids and wanted its sales representatives to prioritize and visit those providers more frequently. As representative examples, Endo gave "A" letter grades to the following Tennessee providers (many of whom were located in East Tennessee) who were either ultimately convicted or had disciplinary action taken against their professional license related to their controlled substance prescriptions:

---

416 ENT000066133 (emphasis added).

417 ENDO-OPIOID_MDL-04950309 (emphasis added).

418 *See, e.g.*, ENDO-OR-CID-00142980 (2011 call list listing Abdelrahman Mohamed, James Pogue, the "McNeil Family Practice," Michael Rhodes, Allen Foster, Robert Cochran, Buffy Kirkland, Christina Collins, David Brickhouse, among others); ENDO-OR-CID-00710288 (2012 Opana ER Call Plan listing Abdelrahman Mohamed, Robert Cochran, among others); ENDO-OR-CID-00828180 (2011 call list includes Abdelrahman Mohamed, James Pogue, Allen Foster, Christina Collins, David Brickhouse, among others); ENDO-OR-CID-00094625; ENDO-OR-CID-00203341; OPANA_ER_CALLS_ALL_STATEs_2017019.

Provider Name	City	Action
Bliss, Julie[419]	Powell, TN	License Probation[420]
Foster, Allen[421]	Knoxville, TN	License Revoked[422]
Friend, Brenda[423]	Bristol, TN	License Reprimanded[424]
Han, Yuchun[425]	Chattanooga, TN	License Reprimanded[426]
Lorge, Jill[427]	Knoxville, TN	License Probation[428]
Mohamed, Abdelrahman[429]	Morristown, TN	License Permanently Surrendered, Criminal Conviction for Health Care Fraud[430]
Pickel, Marjorie[431]	Lenoir City, TN	License Probation[432]
Rhodes, Michael A.[433]	Springfield, TN	License Probation,[434] License Revocation[435]

375. Later, Endo used the same provider-targeting concept with a different name. It designated health care providers as Opana ER "Loyalists" and instructed its sales representatives

419 ENDO-OR-CID-00178528 (Region Top 100 HCPs tab).

420 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12123_111717.

421 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

422 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_31234_012712.

423 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

424 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_13499_020217.

425 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

426 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_35053_012914.

427 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

428 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12618_112017.

429 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab); ENDO-OR-CID-01283744 (8/14/09).

430 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_31933_012418.

431 ENDO-OR-CID-00178528 (Region Top 100 HCP's tab).

432 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_7782_111717.

433 ENDO-OR-CID-00781260 (Opana ER tab, row 144); ENDO-OR-CID-00178527 (Region Top 100 HCP's tab).

434 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_37647_052213.

435 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_37647_092115.

to prioritize sales calls to this group.[436] Many of these "Loyalist" providers that Endo identified in Tennessee had practices which showed vibrant red flags of abuse or diversion, including: Dr. Abdelrahman Mohamed,[437] numerous providers affiliated with the Bearden Healthcare clinic,[438] and Dr. Andrew Sugantharaj.[439] Endo also included other notorious providers, such as Dr. Samson Orusa, on sales calls target lists.[440]

376. Endo repeatedly called on other high-volume OxyContin opioid prescribers in Tennessee who were ultimately arrested, convicted, or received professional discipline for conduct related to their prescribing of controlled substances. Endo's sales representatives made a large number of sales calls to problem providers in Tennessee including Dr. Allen Foster,[441] Dr. Frank McNiel,[442] the Bearden Healthcare Clinic, Dr. Abdelrahman Mohamed,[443] Dr. Visu Vilvarajah,[444] Dr. Mirielle Lalanne[445] (who practiced with Dr. Vilvarajah), Dr. James Pogue,[446] Dr. Robert Cochran,[447] Dr. Samson Orusa,[448] Dr. William Williams,[449] Dr. Yuchun Han,[450] Nurse Practitioner

436 ENDO-OR-CID-01339603; *see also*, ENDO-OR-CID-01339610.

437 ENDO-OR-CID-01339610 (row 2237).

438 ENDO-OR-CID-01339610 (row 889).

439 ENDO-OR-CID-01339610 (row 1835); *see also*, https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_25789_011017.

440 ENDO-OR-CID-01349209 (New Goals – Aligned IMS IDs tab).

441 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_31234_012712.

442 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_16119_032018.

443 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_31933_012418.

444 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_9540_032310.

445 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_14207_032310.

446 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_30361_112812.

447 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_3795_031913.

448 https://www.justice.gov/usao-mdtn/pr/45-count-indictment-charges-clarksville-tennessee-physician-massive-opioid-distribution.

449 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1907_962_050615.

450 https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1606_35053_012914.

Donna Smith,[451] Nurse Practitioner Teodora Neagu,[452] Nurse Practitioner Christina Collins,[453] Nurse Practitioner Buffy Kirkland,[454] and Nurse Practitioner Marjorie Pickel.[455]

377. Endo knew that many of these same providers not only prescribed significant quantities of Opana ER, but significant quantities and percentages of *high-dose* Opana ER. Endo knew that the sample of Tennessee health care providers listed below prescribed the following percentages of high-dose Opana ER (>20 mg) among all their Opana ER prescriptions:

- Registered Nurse Mary McDowell – 97%;
- Physician Assistant David Brickhouse – 97%;
- Nurse Practitioner Brandy Burchell – 96%;
- Dr. James Pogue – 95%;
- Dr. Cindy Scott – 95%;
- Nurse Practitioner Christina Collins – 92%;
- Nurse Practitioner Teodora Neagu – 90%;
- Dr. Frank McNiel – 88%;
- Dr. Robert Cochran – 82%; and
- Dr. Michael Rhodes – 80%.[456]

[451] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_11729_081415.

[452] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12684_111717.

[453] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_12828_030118.

[454] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_10475_051117.

[455] https://apps.health.tn.gov/DisciplinaryExclusion/boardorder/display/1702_7782_111717.

[456] ENDO-OR_MASS_CIDS-00000047.

378. *In 2008 alone*, Endo called on Dr. Allen Foster at least *68* times,[457] Dr. Frank McNiel and the Bearden Healthcare Clinic at least *110* times,[458] Dr. Visu Vilvarajah at least *45* times,[459] Dr. Mirielle Lalanne at least *47* times,[460] Dr. Robert Cochran at least *49* times,[461] Dr. Abdelrahman Mohamed at least *45* times,[462] Dr. James Pogue at least *38* times,[463] Dr. William J.

---

[457] OPANA_ER_CALLS_ALL_STATEs_2017019 (showing Opana ER sales calls on 1/7/08, 1/14/08, 1/15/08, 1/28/08, 1/29/08, 2/6/08, 2/11/08, 2/18/08, 2/19/08, 2/26/08, 3/3/08, 3/5/08, 3/10/08, 3/18/08, 3/25/08, 3/26/08, 3/31/08, 4/1/08, 4/8/08, 4/8/08 (by 2nd Rep.), 4/14/08, 4/15/08, 4/21/08, 4/28/08, 4/29/08, 5/6/08, 5/13/08, 5/19/08, 5/21/08, 5/27/08, 5/29/08, 6/3/08, 6/9/08, 6/10/08, 6/16/08, 6/17/08, 7/1/08, 7/21/08, 7/21/08 (by 2nd Rep.), 7/29/08, 7/31/08, 8/4/08, 8/7/08, 8/11/08, 8/14/08, 8/18/08, 8/20/08, 8/25/08, 8/27/08, 9/08/08, 9/11/08, 9/18/08, 9/23/08, 10/1/08, 10/6/08, 10/9/08, 10/13/08, 10/28/08, 10/30/08, 11/3/08, 11/5/08, 11/11/08, 11/20/08, 11/25/08, 12/1/08, 12/3/08, 12/9/08, and 12/17/08).

[458] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/4/11, 1/8/08 (4 times), 1/11/08, 1/15/08 (2 times), 1/16/08, 1/30/08 (3 times), 2/4/08 (4 times), 2/7/08, 2/8/08, 2/11/08 (3 times), 2/14/08 (2 times), 2/18/08 (4 times), 2/21/08 (2 times), 2/26/08 (4 times), 2/28/08, 2/29/08, 3/3/08, 3/6/08 (3 times), 3/10/08 (3 times), 3/13/08 (2 times), 3/14/08, 3/17/08 (3 times), 3/19/08, 3/21/08 (5 times), 3/26/08 (5 times), 3/27/08 (3 times), 3/30/08, 4/1/08 (3 times), 4/7/08 (3 times), 4/11/08, 4/14/08 (2 times), 4/15/08, 4/18/08, 4/21/08 (2 times), 4/24/08 (2 times), 4/25/08 (2 times), 4/26/08, 4/29/08 (2 times), 5/1/08, 5/5/08 (2 times), 5/8/08, 5/12/08 (2 times), 5/15/08, 5/16/08, 5/27/08 (3 times), 6/2/08 (3 times), 6/9/08, 6/11/08 (2 times), 6/16/08 (2 times), 6/19/08 (2 times), 6/23/08 (2 times), 6/30/08, 7/10/08, 8/12/08, and 9/19/08).

[459] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/3/08, 1/4/08, 1/9/08 (2 times), 1/14/08, 1/28/08, 2/6/08, 2/14/08, 2/21/08, 2/25/08, 3/5/08, 3/6/08, 3/10/08, 3/18/08, 3/20/08, 3/24/08, 3/27/08, 4/3/08, 4/10/08, 4/14/08, 4/21/08, 4/29/08, 5/1/08, 5/13/08, 5/14/08, 5/27/08 (2 times), 6/11/08, 6/30/08, 7/18/08, 7/25/08 (2 times), 7/29/08, 8/11/08, 8/22/08, 9/3/08 (2 times), 9/19/08, 10/1/08, 10/3/08, 10/20/08, 10/23/08, 11/5/08, 11/13/08, 11/25/08, and 12/15/08).

[460] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/3/08, 1/4/08, 1/9/08 (2 times), 1/14/08, 1/27/08, 1/28/08, 1/29/08, 2/6/08, 2/14/08, 2/21/08, 2/25/08, 3/5/08, 3/6/08, 3/10/08 (2 times), 3/18/08, 3/20/08, 3/24/08, 3/27/08, 4/3/08, 4/10/08, 4/14/08, 4/21/08, 4/29/08, 5/1/08, 5/13/08, 5/14/08, 5/27/08 (2 times), 6/11/08, 6/30/08, 7/18/08, 7/25/08 (2 times), 7/29/08, 8/11/08 (2 times), 8/20/08, 8/22/08, 9/3/08 (2 times), 9/19/08, 10/1/08, 10/3/08, 10/6/08, 10/20/08, 10/23/08, 10/29/08, 11/5/08, 11/13/08, 11/24/08, 11/25/08, and 12/15/08).

[461] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/3/08, 1/8/08, 1/29/08, 1/30/08, 2/25/08, 3/5/08, 3/11/08, 3/18/08, 3/25/08, 4/3/08, 4/15/08, 5/1/08, 5/7/08, 5/15/08, 5/27/08, 5/30/08, 6/4/08, 6/12/08, 7/2/08, 7/9/08, 7/10/08, 7/17/08, 7/23/08, 7/31/08, 8/5/08, 8/20/08, 8/27/08, 8/29/08, 9/3/08, 9/8/08, 9/11/08, 9/15/08, 9/22/08, 9/29/08, 10/1/08, 10/6/08, 10/08/08, 10/13/08, 10/15/08, 10/22/08, 10/23/08, 10/27/08, 11/3/08 (2 times), 11/11/08, 11/17/08, 12/2/08, 12/12/08, and 12/16/08).

[462] OPANA_ER_CALLS_ALL_STATEs_2017019 (showing Opana ER sales calls on 1/10/08, 1/17/08, 2/5/08, 2/12/08, 2/22/08, 2/28/08, 3/4/08, 3/12/08, 3/20/08, 3/25/08, 3/31/08, 4/15/08, 5/1/08 (2 times), 5/19/08, 5/30/08, 6/3/08, 6/17/08, 6/23/08, 7/1/08, 7/8/08, 7/11/08, 7/17/08, 7/24/08, 7/25/08, 8/7/08, 8/15/08, 8/19/08, 9/11/08, 9/12/08, 9/25/08, 9/26/08, 10/2/08, 10/3/08, 10/7/08, 10/20/08, 11/4/08, 11/6/08, 11/14/08, 11/18/08, 11/21/08, 12/2/08, 12/11/08, 12/15/08, and 12/30/08).

[463] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/4/08, 2/1/08, 2/5/08, 2/14/08, 2/28/08, 3/10/08, 3/17/08, 3/18/08, 3/27/08, 4/7/08, 4/14/08, 4/21/08, 5/5/08, 5/15/08, 5/1/9/08, 6/2/08, 6/10/08, 6/20/08, 6/27/08, 7/13/08, 7/14/08, 7/17/08, 8/1/08, 8/18/08, 9/4/08, 9/23/08, 10/2/08, 10/14/08, 10/23/08, 10/24/08, 10/27/08, 11/7/08, 11/10/08, 11/17/08, 11/24/08, 11/25/08, 12/12/08, and 12/19/08).

Williams at least *38* times,[464] Dr. Yuchun Han at least *31* times,[465] Dr. Samson Orusa at least *15* times,[466] Nurse Practitioner Marjorie Pickel at least *29* times,[467] and Nurse Practitioner Teodora Neagu at least *18* times.[468]

379. Endo recognized that many of these Tennessee providers were integral to increasing Endo's sales. The company knew that Dr. Abdelrahman Mohamed, Dr. James Pogue, Dr. Frank McNiel, Dr. Andrew Sugantharaj, Dr. Robert Cochran, Dr. William J. Williams, Dr. Yuchun Han, Nurse Practitioner Donna Smith, Nurse Practitioner Jill Lorge, Nurse Practitioner Brenda Friend, Nurse Practitioner Julie Bliss, Nurse Practitioner Teodora Neagu, Nurse Practitioner Christina Collins, Nurse Practitioner Brandy Burchell, Nurse Practitioner Buffy Kirkland, Nurse Practitioner Marjorie Pickel, and Nurse Practitioner Brenda Friend, among others, "contribut[ed] to [the] top 50% of [Endo's Opana ER] Business" nationwide.[469]

380. In fact, of the 1,612 providers nationwide who contributed to the top 50% of Endo's Opana ER business, 169—more than 10%—were from Tennessee.

---

[464] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/3/08, 1/7/08, 1/14/08, 1/28/08, 2/12/08, 2/13/08, 2/18/08, 3/12/08, 3/17/08, 3/24/08, 4/8/08, 4/16/08, 4/23/08, 4/29/08, 5/2/08, 5/6/08, 5/14/08, 5/28/08, 6/12/08, 6/13/08, 6/25/08, 7/2/08, 7/9/08, 7/23/08, 8/6/08, 8/13/08, 8/20/08, 8/27/08, 9/4/08, 9/10/08, 9/24/08, 9/29/08, 10/7/08, 10/14/08, 10/30/08, 11/13/08, 11/19/08, and 12/17/08).

[465] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/2/08, 1/10/08, 1/15/08, 1/31/08, 2/11/08, 2/18/08, 2/25/08, 2/27/08, 3/5/08, 3/13/08, 3/26/08, 4/2/08, 4/8/08, 4/10/08, 4/17/08, 4/22/08, 4/29/08, 5/8/08, 6/2/08, 6/16/08, 6/19/08, 7/14/08, 8/7/08, 8/13/08, 8/21/08, 9/4/08, 9/10/08, 9/22/08, 10/8/08, 11/19/08, and 12/17/08).

[466] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/8/08, 1/30/08, 3/19/08, 4/11/08, 4/22/08, 4/30/08, 5/22/08, 6/10/08, 6/18/08, 7/3/08, 7/8/08, 7/21/08, 7/22/08, 9/24/08, and 10/2/08).

[467] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/7/08, 1/9/08, 1/11/08 (2 times), 1/17/08, 1/30/08, 2/6/08, 2/13/08, 2/14/08, 2/15/08, 2/22/08, 2/26/08, 2/29/08, 3/14/08, 4/9/08, 4/16/08, 4/24/08, 5/8/08, 6/20/08, 7/22/08, 7/25/08, 8/27/08, 9/30/08, 10/15/08, 10/30/08, 11/20/08, 11/25/08, 12/4/08, and 12/18/08).

[468] OPANA_ER_CALLS_ALL_STATEs_20171019 (showing Opana ER sales calls on 1/10/08, 2/5/08, 2/12/08, 2/20/08, 2/27/08, 2/28/08, 3/4/08, 3/20/08, 3/25/08, 4/10/08, 4/15/08, 5/1/08, 6/16/08, 7/10/08, 7/24/08, 8/12/08, 8/27/08, and 9/19/08).

[469] ENDO-OR-CID-01196574 (column O).

381. Endo was keenly aware of the contribution of high prescribers to its opioid sales and evaluated most of its major decisions with this in mind. For example, when Endo was determining whether it would remove the 7.5 mg and 15 mg Opana ER from the market in anticipation of Actavis's entry with these generic doses, the company checked to see whether its top Opana ER prescribers, including Dr. Abdelrahman Mohamed and other red flag Tennessee providers, prescribed significant quantities of these doses before making its decision.[470]

382. Endo sales representatives regularly ignored internal reports of red flags for abuse or diversion related to health care providers being called upon.

383. Endo's sales representatives and district managers observed and ignored red flags for abuse or diversion of opioids, including Opana ER, in sales calls with providers who would ultimately be arrested, convicted, or have their professional licenses disciplined for conduct related to their prescribing of controlled substances.

384. First, Endo trained its sales representatives to intimately understand the provider's practice and to develop detailed profiles of the providers they called upon in advance of sales calls.[471]

385. Second, signs of abuse or diversion, such as cars with license plates from distant places in pharmacy parking lots, packed waiting rooms, disproportionate numbers of cash-paying patients, signs directed to cash-paying patients, and providers who were never present, would have been readily apparent to Endo's sales representatives when they visited practice locations in Tennessee—especially when they made repeated sales calls.

[470] ENDO-OR-CID-00472627 (Master List tab).

[471] ENDO-OR-CID-01332410.

386. Third, Endo had sales data that told the company exactly which providers were prescribing high volumes of Opana ER and other opioids.

387. As an example, Endo sales representatives repeatedly called on Dr. Abdelrahman Mohamed of Morristown until November 30, 2016.[472] Dr. Mohamed, who was one of the top prescribers of Opana ER in the country, showed signs of abuse and diversion of opioids at his clinic before he was arrested for health care fraud involving opioids. Dr. Mohamed alone prescribed *53% of all the 1,140,338 Opana ER pills prescribed in Morristown between 2007 and 2014.*[473]

388. As recounted in his criminal plea agreement, between January 2012 and September 2016, Dr. Mohamed and his wife scheduled "appointments" for between 40 to 60 pain management patients per day during the estimated six-hour period that Dr. Mohamed worked. To deal with the high volume, on many occasions, employees were instructed to line the patients up in the hallway outside of Dr. Mohamed's office. An employee would then escort the first patient into Dr. Mohamed's office for a one- to two-minute open-door meeting (where no real examination or assessment of the patient could possibly occur), and then the employee would hand Dr. Mohamed a partially completed prescription for an opioid, which he signed and handed to the patient. Dr. Mohamed and his staff repeated this drive-by doctoring until all waiting patients had received an opioid prescription. Each patient was then scheduled for another appointment the following month when the process was repeated. As part of his plea agreement, Dr. Mohamed

[472] ENDO-OR-MASS_CIDS-000001; OPANA_ER_CALLS_TN_20191019.

[473] ENDO-OR_MASS_CIDS-00000047.

admitted that he issued thousands of prescriptions for opioids outside the scope of ordinary medical practice.[474]

389. Endo was not a passive participant, but instead actively worked to find pharmacies willing to fill the obscene volume of Dr. Mohamed's Opana ER prescriptions before he was arrested.[475] On March 28, 2012, Endo sprang into action and found pharmacies that would fill Dr. Mohamed's Opana ER prescriptions after one of its sales representatives stated:

> This is my top writer he is having a hard time getting Opana for his current patients and now [sic] switching them over to other medications. Need more information let me know.[476]

390. As another example, Endo sales representatives repeatedly called on Dr. Samson Orusa at his office location at 261 Stonecrossing Drive in Clarksville, Tennessee. Endo placed him on its national provider "target list"[477] before he was belatedly placed on Endo's no-call list.[478] Dr. Orusa is currently under federal indictment for 22 counts of unlawful distribution of a controlled substance outside the bounds of professional medical practice, 13 counts of healthcare fraud, and 9 counts of money laundering.[479] The 2018 indictment alleges that Dr. Orusa saw 50 to 60 patients or more each day.[480]

391. Endo's sales representatives observed or should have observed red flags for abuse or diversion at Dr. Orusa's clinic, which as shown below, was a dilapidated, trailer-like structure

---

474 https://www.justice.gov/usao-edtn/pr/physician-owner-hnc-and-wife-sentenced-health-care-fraud-offenses-involving.

475 ENDO-OPIOID_MDL-00400521.

476 ENDO-OPIOID_MDL-00400524.

477 ENDO-OR-CID-00142978.

478 *See* ENDO-OR-CID-01305194 (P2-Mid-Atlantic tab) (not showing Dr. Orusa on removal list in 2012); ENDO-OPIOID_MDL-05551939 (Nation tab) (not showing Dr. Orusa on removal list in 2013).

479 Chris Smith, *Pain Clinic Doctor Arrested in Opioid Fraud Scheme Plans to Fight Charges*, CLARKSVILLE LEAF CHRONICLE, *available at* https://www.theleafchronicle.com/story/news/crime/2018/12/14/pain-clinic-doctor-samson-orusa-arrested-opioid-fraud-scheme/2309993002/.

480 https://www.justice.gov/usao-mdtn/pr/45-count-indictment-charges-clarksville-tennessee-physician-massive-opioid-distribution.

that had a sign on the outside that stated “NEW PATIENTS & WALK INS WELCOME,” had a phone number to reach the doctor 24 hours a day, and had a message for cash-paying patients on the front door.

392. Endo not only targeted high volume and suspect Opana ER prescribers in Tennessee, it specifically pursued high volume and suspect OxyContin prescribers as well. When OxyContin was reformulated to become more resistant to certain forms of abuse, pill mills and abusers in Tennessee sought a new highly-potent, easy-to-abuse extended release opioid and Endo capitalized on the opening.

393. Even before the reformulated OxyContin came onto the market in 2010, Endo knew that abuse of Opana ER was a growing problem in Tennessee. As examples, based on a news report forwarded internally on March 13 and 23, 2009, Endo knew that abuse of Opana ER was on the rise in Tennessee and that the drug was responsible for several fatal overdoses according to local law enforcement.[481] Endo's senior compliance employees were notified by a Tennessee health care provider the same day of five recent "Opana" deaths in Tennessee from "recreational

[481] END00361415; END00360804.

use,"[482] one of which was an opioid-naïve 18-year-old who crushed and snorted a relative's prescription.[483]

394. Likewise, TennCare, the State Medicaid agency, informed Endo in an e-mail sent on July 30, 2010 that:

> [B]ased upon information provided by the Tennessee Bureau of Investigation (TBI), *TennCare has concerns about the growing abuse of Opana ER.* As you may be aware, *there is a process [known] as "crisping" that evidently allows individuals to free the oxymorphone*.[484]

395. In August 2010, almost immediately after OxyContin's reformulation launch, Endo knew that the significant increase in Opana ER prescriptions was a result of customer dissatisfaction with the new OxyContin formulation.[485]

396. Within the next two months, Endo had already recognized that Opana ER was experiencing "[a]ll-time highs in weekly [prescription] volume . . . due to current trends and patient dissatisfaction with new OxyContin formulation."[486]

397. Instead of putting the brakes on its marketing to suspect providers in Tennessee after these and other warnings, Endo accelerated and even celebrated implementation of its marketing that targeted high OxyContin and other opioid prescribers.[487]

398. Endo continued to deceptively market Opana ER after it knew that the company was benefiting from both its marketing and patients who switched from OxyContin to make Opana ER their abused or diverted opioid of choice. By February 2011, Endo had concluded that the

---

482 END00361415.

483 END00361415.

484 ENDO-OR-CID-00973907 (emphasis added).

485 ENDO-CHI_LIT-00545593 (slide 2 of 32).

486 ENDO-OR-CID-00408581 (slide 11 of 34).

487 *See* ENDO-OR-CID-00584357 (slide 15 of 21).

significant increase in Opana ER prescriptions in late 2010 was due to (1) the launch of the reformulated OxyContin in August 2010 and (2) its own aggressive marketing efforts.[488] By that point, the company had also concluded that Opana ER was showing the most gain during OxyContin's loss[489] and that "abuse behavior" was driving decline in OxyContin use.[490]

399. Endo knew "[t]he introduction of an abuse-deterrent formulation of OxyContin in August 2010 coincided with a documented increase in reported abuse rates of Opana ER[,]"[491] and it knew the Deputy Assistant Administrator for the Drug Enforcement Administration stated that Opana ER was going to be the next OxyContin epidemic on June 27, 2011.[492]

400. Endo was told directly about the growing Opana ER problem in Tennessee on other occasions. On July 26, 2011, an Endo representative attended an "East Tennessee Prescription Drug Summit" held in Knoxville at the University of Tennessee Conference Center with representatives from federal, state, and local law enforcement and other pharmaceutical manufacturers. The Endo representative who attended reported back to Endo's senior compliance employees that:

> Joe Rannazzisi [Then-Deputy Assistant Administrator] of DEA briefly cited OpanaER as a product that is surfacing more and more as a drug of diversion (When he mentioned this, there was an audible murmur of "yes", "that's right", etc. from several members of the audience.)[493]
> ….
>
> In eastern Tennessee in 2009, 42% of admissions to drug treatment facilities were for abuse of opioids.[494]

---

488 ENDO-OR-CID-00182446, -471 (document is marked "draft" but was presented internally; *see* ENDO-OR-CID-00182441).

489 ENDO-OR-CID-00182463.

490 ENDO-OR-CID-00182464.

491 ENDO-OR-CID-00428201.

492 ENDO-OR-CID-00042443.

493 ENDO-OPIOID_MDL-00395969.

494 ENDO-OPIOID_MDL-00395970.

401. In a July 26, 2011 e-mail with the subject line of "Opana ER Opportunities," Endo's Regional Business Director noted:

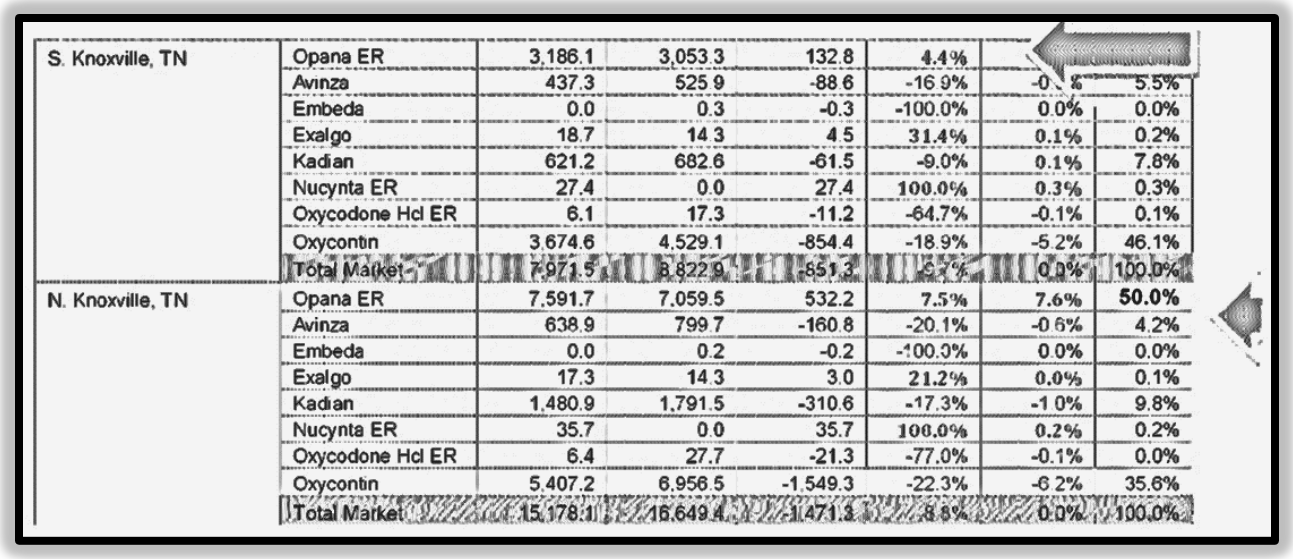
> [T]he Mid-Atlantic [region] contributes more Opana ER TRx volume than the other five regions, and *we have a number of footprints that have extremely high market share even beyond OxyContin*[.][495]

402. Many of these successful Endo sales territory subdivisions or "footprints" in the Mid-Atlantic region were based in East Tennessee and specifically the Knoxville area. In a November 18, 2011 e-mail, Endo's sales managers congratulated sales representatives in both the South and North Knoxville territories:

> Special congratulations go to [Sales Representatives' names] in the Knoxville South territory for reaching the 40% share of market and extra special congratulations go to [Sales Representatives' names] in our Knoxville North territory for making it all the way to 50% of the long-acting opioids market!
>
> Thank you for your leadership and your ability to demonstrates the big things that are possible with Opana ER.
>
> See the details below:[496]

[495] ENDO-OR-CID-00079469 (emphasis added); *See also*, ENDO-OR-CID-00178527 (January 4, 2011 e-mail stating "The Mid-Atlantic [region where Tennessee is located] is the greatest contributor to Opana ER TRx's in the country vs. the other regions: lets widen that gap and set ourselves up for success in 2011!")

[496] ENDO-OR-CID-00201117 (emphasis in the original).



S. Knoxville, TN	Opana ER	3,186.1	3,053.3	132.8	4.4%		5.5%
	Avinza	437.3	525.9	-88.6	-16.9%	-0.4%	0.0%
	Embeda	0.0	0.3	-0.3	-100.0%	0.0%	0.2%
	Exalgo	18.7	14.3	4.5	31.4%	0.1%	7.8%
	Kadian	621.2	682.6	-61.5	-9.0%	0.1%	0.3%
	Nucynta ER	27.4	0.0	27.4	100.0%	0.3%	0.1%
	Oxycodone Hcl ER	6.1	17.3	-11.2	-64.7%	-0.1%	46.1%
	Oxycontin	3,674.6	4,529.1	-854.4	-18.9%	-5.2%	100.0%
	Total Market	7,971.5	8,822.9	-851.3	-9.7%	0.0%	
N. Knoxville, TN	Opana ER	7,591.7	7,059.5	532.2	7.5%	7.6%	**50.0%**
	Avinza	638.9	799.7	-160.8	-20.1%	-0.6%	4.2%
	Embeda	0.0	0.2	-0.2	-100.0%	0.0%	0.0%
	Exalgo	17.3	14.3	3.0	21.2%	0.0%	0.1%
	Kadian	1,480.9	1,791.5	-310.6	-17.3%	-1.0%	9.8%
	Nucynta ER	35.7	0.0	35.7	100.0%	0.2%	0.2%
	Oxycodone Hcl ER	6.4	27.7	-21.3	-77.0%	-0.1%	0.0%
	Oxycontin	5,407.2	6,956.5	-1,549.3	-22.3%	-6.2%	35.6%
	Total Market	15,178.1	16,649.4	-1,471.3	-8.8%	0.0%	100.0%

403. Endo continued marketing to high-volume prescribers of OxyContin and other opioids in Tennessee throughout the year. As of December 23, 2011, both the East and West Tennessee districts were in the top 10 nationwide for Opana ER prescriptions for the previous month. The East Tennessee district had more Opana ER prescriptions than any other districts in the country.[497]

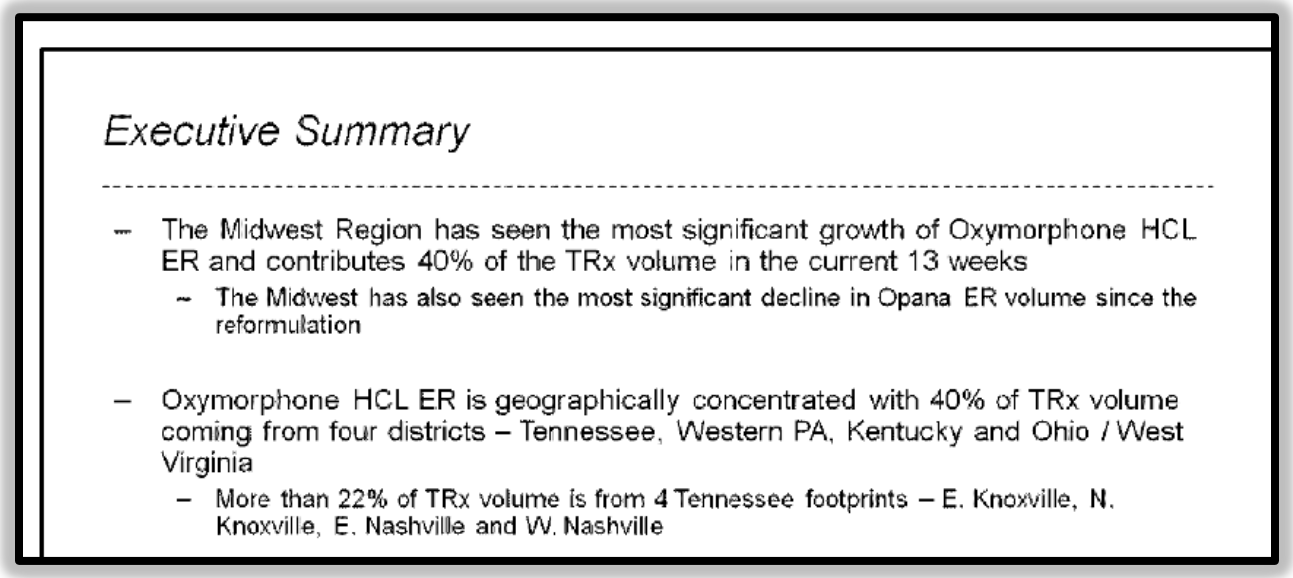
404. Even the makers of generic Opana ER took note of Endo's success and began personal promotion efforts in Knoxville beginning in 2011 in response to Opana ER brand performance trends.[498]

405. In Tennessee, Endo's Opana ER marketing and other conduct created a huge market for oxymorphone through individuals who became addicted to the drug and elevated rates of abuse or diversion from high volume or suspect providers. By 2012, it knew that *22% of the nationwide*

[497] ENDO-OR-CID-00718646; *see also*, ENDO-OR-CID-00343598 (slide 15 of 74).

[498] ENDO-OR-CID-00219144.

prescription volume of extended release oxymorphone was coming from four territories: East Knoxville, North Knoxville, East Nashville, and West Nashville.[499]


Executive Summary

- The Midwest Region has seen the most significant growth of Oxymorphone HCL ER and contributes 40% of the TRx volume in the current 13 weeks
  - The Midwest has also seen the most significant decline in Opana ER volume since the reformulation
- Oxymorphone HCL ER is geographically concentrated with 40% of TRx volume coming from four districts – Tennessee, Western PA, Kentucky and Ohio / West Virginia
  - More than 22% of TRx volume is from 4 Tennessee footprints – E. Knoxville, N. Knoxville, E. Nashville and W. Nashville

406. Endo not only continued to market Opana ER to suspect providers, effectively seeking to make Opana ER their abused or diverted narcotic of choice to prescribe, but it also continued to market Opana ER *as an abuse deterrent opioid* to health care providers despite knowing that:

- the FDA had rejected such claims for its product label;
- the FDA expressly told Endo its claims were misleading and could jeopardize public health;
- intravenous use of the reformulated Opana ER was predicted by Endo's own studies;
- intravenous use of the reformulated Opana ER "could not be prevented" because of oxymorphone's water solubility;
- Endo had withdrawn Opana ER's predecessor, Numorphan, from the market in 1982 following reports of intravenous abuse;
- the reformulated Opana ER was even easier to inject than its old formulation according to its own data;

[499] ENDO-OR-CID-00289933.

- the reformulated Opana ER could be easily manipulated to dose-dump;
- intravenous abuse of Opana ER through cutting was occurring in significant numbers, including through a cluster of individuals in Kingsport, Tennessee and elsewhere who contracted HIV, Hepatitis C, and/or TTP, a rare and serious blood disorder after needle sharing; and
- Tennesseans were dying from overdoses caused by intravenous use of Opana ER.

407. Endo's data showed that abuse of original Opana ER was worse in Tennessee than in any other state in the country, yet it continued to market both the original and reformulated Opana ER as an abuse deterrent[500] in Tennessee.

408. Endo knew that the reformulated Opana ER had *over three times* the prevalence rate for abuse in Tennessee than the original formulation and yet it promoted reformulated Opana ER as having abuse-deterrent properties or a lower abuse profile.[501]

409. In particular, Endo knew that a disproportionately large number of abusers in Tennessee were injecting Opana ER. Endo's own data showed that the reformulated Opana ER was even more susceptible to intravenous abuse than the original,[502] that it was reported to be injected *1,494% more* times in Tennessee than Endo's original formulation of Opana ER,[503] and that the "[t]endency towards greater intravenous abuse in Tennessee has been documented in the NAVIPPRO system as far back as 2008, independent of the abuse of OPANA ER and before the

[500] https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM545762.pdf (slide 86 of 149).

[501] ENDO-OPIOID_MDL-04950334.

[502] ENT000023403; ENDO-OR-CID-00082828; ENDO-OR-CID-00010938; *see also*, ENDO-OR-CID-00019657; ENT000048880 (emphasis added).

[503] ENDO-OPIOID_MDL-04951037 (slides 17-18 of 36).

reformulation of OPANA ER."[504] Endo nevertheless marketed the reformulated Opana ER as abuse deterrent to health care providers in Tennessee, including suspect or problem providers.

410. Endo's marketing of Opana ER as an abuse deterrent or as less prone to abuse continued in early 2010 after the company knew that a disproportionate number of individuals in Tennessee were paying for Opana ER prescriptions with cash[505]—a red flag for abuse or diversion because, among other reasons, cash-purchased prescriptions are not subject to quantity restrictions like those purchased through insurance or a third-party payor.

411. Later in 2010 and into 2011, Endo's promotion of Opana ER as abuse deterrent or less prone to abuse continued after the company knew that numerous individuals in Tennessee had switched from OxyContin to Opana ER as their abused or diverted opioid of choice.

412. Endo also chose not to change its marketing in 2012 after the company had specific knowledge of significant Opana ER abuse in Tennessee. Through a February 22, 2012 abuse surveillance report, Endo knew that in 2011, Tennessee had some of the highest rates of 30-day abuse of Opana ER in the country.[506]

413. Endo decided not to change its marketing after being told directly by its sales representatives about significant abuse of the original formulation of Opana ER. In a June 25, 2012 email, Endo's sales representatives in Tennessee reported:

> We believe that several of the patients in our footprint were abusing the previous formulation of Opana ER. Here are some signs we have witnessed: Patients requested the old formulation of Opana ER at the pharmacy, asked their providers in some instances to switch them from 40 mg of Opana ER to generic 15 mg, and they complained about adverse events so they could be switched from 30 mg of

---

504 https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM545762.pdf (slide 87 of 149).

505 ENDO-OR-CID-01202894 (Opana ER tab showing 8.04% of Opana ER prescriptions in cash for East Nashville territory and 7.26% of Opana ER prescriptions in cash for the North Knoxville territory).

506 ENDO-OR-CID-00694685, -716.

> Opana ER to two 15 mg pills of the generic formulation. I have even had pharmacies tell me that patients are calling them acting like they are with the Opana ER pharmacy locater service. They are asking if the pharmacy in question carries the old formulation of Opana ER.[507]

414. Likewise, Endo continued to aggressively push Opana ER in Tennessee as an abuse deterrent or as less prone to abuse despite knowing about the outbreak of individuals who developed a rare blood disorder following intravenous use of Opana ER beginning on August 14, 2012.[508]

415. Endo continued its deceptive marketing even after it learned about a Tennessee patient's death from sepsis caused by injecting Opana ER. On October 1, 2012, Endo's Vice President for Pharmacovigilance and Risk Management received the following report:

> [Initials Withheld] 29 y.o. Admitted 8/3 with sepsis. Blood cultures positive for Pseudomonas aeruginosa. *Admitted IV drug abuse specific to Opana.* Had tricuspid endocarditis and metastatic lung abscesses. Local CT surgeons declined consideration for cardiac surgery. She was transferred to [redacted] in [redacted] for second opinion where I can confirm she died on [redacted]. She did not have hematologic findings suggesting microangiopathic TTP-HUS like syndrome.[509]

416. Endo continued its deceptive marketing even after it knew that another Tennessee patient died from injecting Opana ER. On December 8, 2012, almost a year after the reformulation, Endo's Vice President of Pharmacovigilance and Risk Management sent an internal e-mail to Endo's Safety Department stating in part:

> [T]he patient was a male in his early 30s with the initials [withheld]. He is from the community around [redacted], TN. He was being treated at this facility for low back pain due to degenerative joint disease and other spinal problems. His Opana ER was recently increased from 30mg to 40mg because of increasing pain. He also had recently suffered burns due to an accidental gasoline fire. However, the Opana ER was not being used to treat that.

---

507 ENDO-OR-CID-00954372.

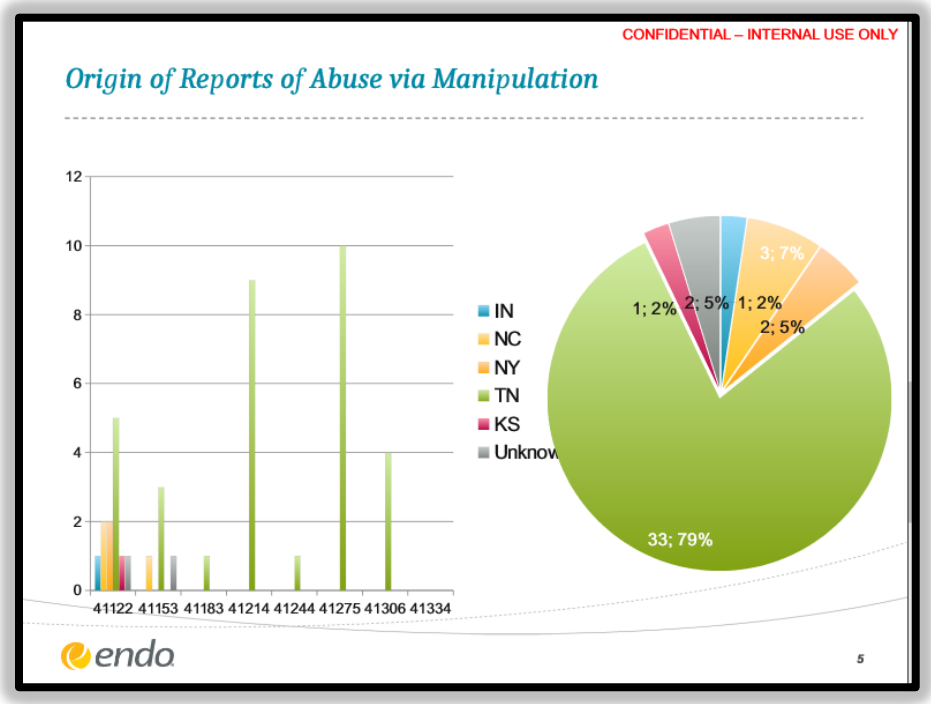
508 ENDO-OR-CID-01026817 (slide 6 of 13); ENDO-OR-CID-01222026.

509 ENDO-OR-CID-00525258 (emphasis added).

The patient was found by his partner dead in the bathtub with a needle in his arm. He had apparently melted Opana ER and injected it[.][510]

417. Endo maintained its destructive course of marketing in Tennessee in 2013, after it knew:

- that one of the individuals who injected Opana ER and developed TTP in Tennessee died from complications from Hepatitis C and sepsis;[511]
- of 33 cases of confirmed or suspected TTP or a TTP-like illness from Opana ER intravenous users;[512]
- of numerous surveillance reports from Internet postings that spoke to the ease of abusing Opana ER by injection[513] and recipes to dose-dump the medication;[514]
- of a report of abuse of Opana ER that showed that Tennessee's 33 reports of abuse accounted for *79% of all incidents* during that period;[515] and



510 ENDO-OR-CID-00516187 (emphasis added).

511 ENDO-OR-CID-01205491.

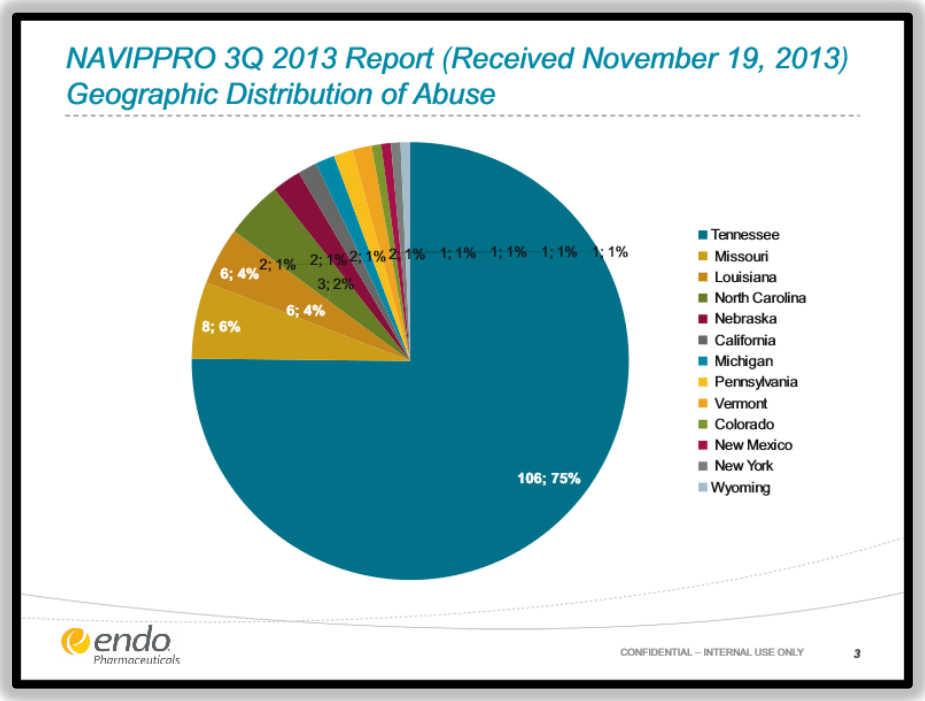
512 ENDO-OR-CID-00129895; ENDO-OR-CID-00130031.

513 ENDO-OR-CID-00518507.

514 ENDO-OR-CID-00546057.

515 ENDO-OR-CID-00670966 (slide 6 of 7).

- of another report of Opana ER abuse from across the country that showed that *75% of all incidents* or 106 reports of abuse occurred in Tennessee.[516]



418. Over the next three years from 2014-2017, Endo continued its aggressive and deceptive marketing practices, including touting Opana ER as an abuse deterrent, after it became aware of:

- a CDC report that connected a significant outbreak of HIV in Scott County, Indiana that spread because of intravenous abuse of Opana ER;[517]

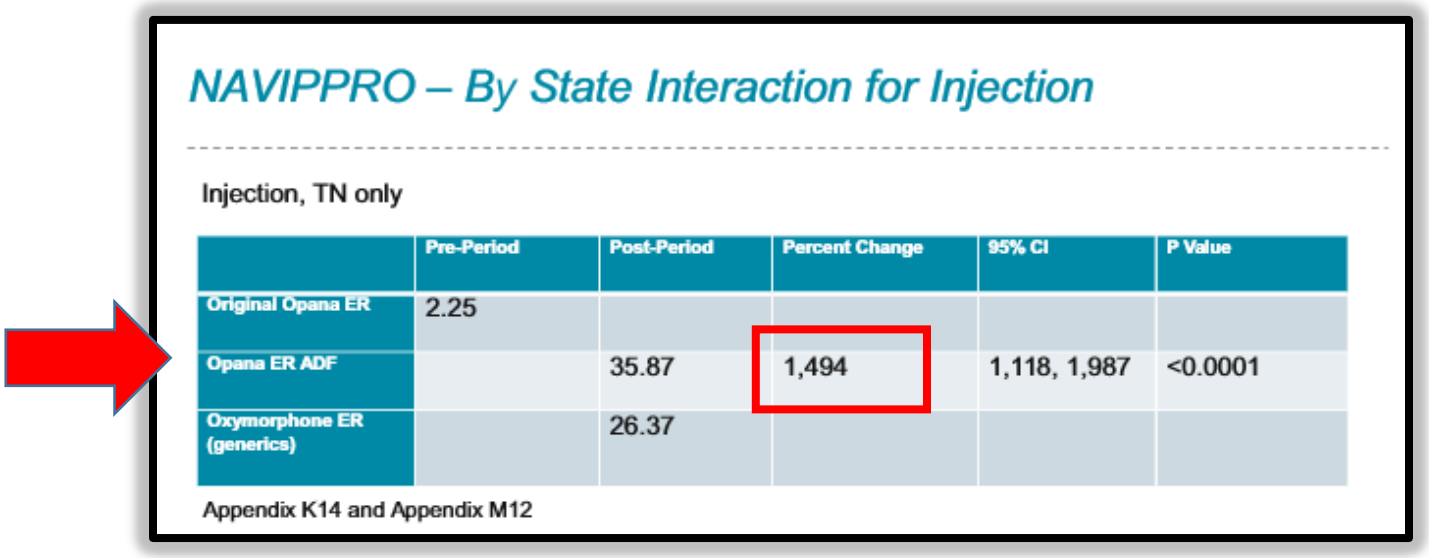
- a separate report that found a *364%* increase in new Hepatitis C cases in Tennessee, Kentucky, Virginia, and West Virginia in individuals who used

[516] ENDO-OR-CID-01010979 (slide 3 of 12).

[517] Caitlin Conrad, *Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone – Indiana, 2015, Morbidity and Mortality Weekly Report (MMWR),* CENTERS FOR DISEASE CONTROL AND PREVENTION, 64(16); 443-444 (May 1, 2015), *available at* https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm.

drugs intravenously,[518] which the lead CDC author *blamed on Opana ER*;[519] and

- an internal report showing a *1,494% increase* in Opana ER injection rates in Tennessee for the reformulated version over the original version.[520]



NAVIPPRO – By State Interaction for Injection

Injection, TN only

	Pre-Period	Post-Period	Percent Change	95% CI	P Value
Original Opana ER	2.25				
Opana ER ADF		35.87	1,494	1,118, 1,987	<0.0001
Oxymorphone ER (generics)		26.37			

Appendix K14 and Appendix M12

419. Endo's efforts to thwart abuse and diversion of Opana ER and other opioids were anemic at best. The compliance policies it did create[521] were inadequate, inconsistently administered, and all too often yielded to Endo's emphasis on marketing and generating new opioid prescriptions. It was much easier and financially rewarding for Endo to continue marketing to suspect providers or known pill mills than to acknowledge the damage being inflicted on Tennessee.

---

518 *Increases in Hepatitis C Virus Infection Related to Injection Drug Use Among Persons Aged <30 Years - Kentucky, Tennessee, Virginia, and West Virginia, 2006-2012*, MORTALITY AND MORBIDITY WEEKLY REPORT, CENTERS FOR DISEASE CONTROL AND PREVENTION (May 7, 2015), *available at* https://content.govdelivery.com/accounts/USCDC/bulletins/1032201.

519 ENDO-OR-CID-01343662, -663 (emphasis added).

520 ENDO-OPIOID_MDL-04951037 (slide 20 of 36) (showing a 62.9% increase in injection rates in all states except Tennessee).

521 ENDO-OR-CID-01297075.

420. Endo did not take compliance seriously. The company's process for removal of a prescriber from call lists had to be initiated by the sales representative, who was financially disincentivized from reporting a high-volume prescriber, and then approved by Endo's Compliance and Legal Department.[522]

421. In the rare instance a sales representative reported a provider for red flags for abuse or diversion, Endo often did nothing about it.

422. For example, in 2007, an Endo district manager e-mailed the Vice President of Ethics and Corporate Compliance regarding her concern about Dr. Frank McNiel of Bearden Healthcare, one of the highest prescribers of controlled substances in Tennessee. The district manager reported:

> [I] am the manager in NC/TN and I have an issue with one of our prescribers listed on our pharma call plan. *There is a physician in Knoxville—Dr. Frank McNiel that is prescribing around 80-100 scripts of extended release opioids a week and 90% of those scripts are for OxyContin*. . . . I have been to the office numerous times and *lately Dr. McNiel has not been seeing patients*. On an average day he sees around 8-10 patients and *has many PA's that rotate through his office and then disappear after 6 months*.
>
> *He has a full staff and his office is always packed. I spoke to the local pharmacist and she stated that a lot of Dr. McNiel's patients pay cash for Oxycontin*. I have not witnessed any suspect behavior first hand in the office but I wanted your opinion on what we should do regarding the situation. *Dr. McNiel prescribes almost 3 times what the average PCP writes and I am not sure how legitimate his practice appears to be. As an example, Dr. McNiel has written 3800 scripts of Oxycontin through Sept of this year which seems almost impossible for even a pain clinic[.]*[523]

423. Endo's Vice President of Ethics and Compliance brushed off the district manager's concerns that Dr. McNiel had prescribed an "impossible" number of OxyContin prescriptions during a set time, and responded:

---

[522] ENDO-OR-CID-00475341; *see also*, ENDO-OR-CID-01055169.

[523] ENDO-OPIOID_MDL-05543020 (emphasis added).

> Thanks for your note. We actually looked into Dr. McNeil [sic] earlier this year and didn't find any evidence of suspected diversion. Please let me know if you have any additional information about the practice.[524]

424. Endo made a cost/benefit decision about removing Dr. Frank McNiel, who was a significant OxyContin prescriber and thus a significant Opana ER prescriber target. Dr. McNiel accounted "for 1/5 of the opioids that [were] written"[525] in the Knoxville territory so removing him from the list would have meant giving up on one of the biggest providers in terms of sales potential for Opana ER in Tennessee. Endo eventually did place Dr. Frank McNiel on its removal list, but waited until 2010[526]—three years after Endo ignored the district manager's red flags report. Endo continued to keep providers closely associated with Dr. McNiel on its Opana ER target list as late as 2015.[527]

425. Endo used sales data to influence its decisions about removing suspect providers from call lists. Notably, before making a decision whether to exclude a provider from sales calls, Endo wanted to know "[w]hat % of the territory totals does the prescriber represent by product (e.g. Dr. X's OPANA ER prescriber represent X% of the total territory OPANA ER goal, etc.)?"[528] Endo also analyzed the "recent call history and script data across all brands" for each prescriber who was submitted for removal and evaluated their prescription history when they were removed to see if they should be called on again—*even if they were removed because of suspected abuse or diversion related to their practices*.[529]

---

524 ENDO-OPIOID_MDL-05543021.

525 ENDO-OPIOID_MDL-05543020.

526 ENDO-OR-CID-1297078 (P2-Mid-Atlantic tab, Submitted column).

527 ENDO-OR-CID-01348972.

528 ENDO-OR-CID-00850542.

529 ENDO-OR-CID-01297078 (INSTRUCTIONS & GUIDELINES tab and P2 – Mid-Atlantic tab).

426. Endo ultimately (and belatedly) removed a tiny fraction of the total targeted providers with practices that showed red flags for abuse or diversion. By 2012, Endo had placed *only 13* Tennessee providers on its removal list,[530] which only started in 2010—*four years* after Opana ER came onto the market.[531]

427. And in the few instances when Endo stopped calling on a provider, the company simply asked its sales representatives to *stop seeing the specific provider for a specific product*.[532] As a result, Endo's sales representative could and did still make sales calls to that provider on other products, including immediate release Opana.[533] In addition, Endo's sales representatives could and often did still call to the problem provider's associates, subordinates, or supervisees,[534] which was particularly troublesome and inappropriate given that most of the highest prescribers relied heavily on subordinates and supervisees.

428. Even when Endo placed prescribers on its removal list, Endo's sales representatives continued calling on many of these prescribers anyway.[535] And when Endo's Compliance Department was notified of the non-compliance, Endo's response was merely to send a warning letter to any sales representative who called on an excluded provider.[536] Unsurprisingly, Endo's sales representatives did not take the threat of a warning letter seriously. One of its North Carolina

---

530 ENDO-OPIOID_MDL-05580703 (P2 – Mid-Atlantic tab).

531 ENDO-OPIOID_MDL-5551941 (Nation tab Column D).

532 ENDO-OR-CID-00536596; ENDO-OR-CID-01277131, -132 (Details tab, Excluded Products column); ENDO-OR-CID-01277135; ENDO-OR-CID-01277137 (Details tab, Excluded Products column).

533 ENDO-OR-CID-01277137 (Details tab, Excluded Products column, Primary and Secondary columns).

534 *See* ENDO-OR-CID-00505261, -262.

535 ENDO-OR-CID-01276924; ENDO-OR-CID-00412655; ENDO-OR-CID-01277131; ENDO-OR-CID-01277132; ENDO-OR-CID-01277135; ENDO-OR-CID-01277137.

536 ENDO-OR-CID-00412655; ENDO-OR-CID-00475574.

sales representatives conveyed this widely-held sentiment when he stated: "I will probably get a letter sooner or later. *It can go besides the one [sic] other ones . . . .*"[537]

429. In addition to marketing the purported safety, benefits, and efficacy of its opioids to health care providers, Endo also fueled the opioid epidemic in Tennessee through its heavy promotion and use of Opana ER savings cards.[538] Endo's savings cards operated like a coupon to offset the cost of a prescription for a patient. These Opana ER savings cards were used by cash-paying patients,[539] were often used multiple times,[540] were overwhelmingly used to purchase high-dose Opana ER,[541] and were relied on by high-volume prescribers and pain clinics that exhibited credible signs of abuse or diversion of opioids.[542]

430. Opana ER savings cards generated significant revenue for Endo. For example, according to an internal document analyzing Opana ER savings card data from March 2011 to March 2012, Endo's program had a return on investment (ROI) of *28.9 to 1*.[543] Elsewhere, Endo noted that the program's ROI ranged from *1,600* to *9,700%* and that 20% of savings card redemptions were greater than three uses, "indicating increasing brand loyalty."[544]

---

537 ENDO-OR-CID-00475573 (emphasis added).

538 ENDO-OR-CID-00880021 (Redemption Density Map tab showing Tennessee with higher aggregate savings card redemptions than California, New York, or Illinois).

539 *See* ENDO-CHI_LIT-00537588.

540 ENDO-OR-CID-01291065.

541 ENDO-OR-CID-00078247 (Dosage Summary tab).

542 *See, e.g.*, ENDO-OR-CID-00880021 (Prescriber Summary Pharma tab, Mohamed, Abdelrahman 278 redemptions) (line 13073).

543 ENDO-OR-CID-00277702, -704.

544 ENDO-CHI_LIT-00546435 (slide 28 of 86).

431. Endo trained its sales representatives to discuss savings cards on their sales calls with providers because it had evidence that the savings cards would help ensure that the providers' patients continued taking Endo's opioids.[545]

432. Endo deployed a special savings card promotion titled the "Patient Starter Kit Co-pay Savings Card" to get more new patients on Opana ER,[546] which comprised 78.9% of the types of Endo's savings cards used in March 2012.[547] From March 2011 to March 2012, "Opana ER average [new prescription] share increased by 9.5 share points compared to before they were used and when a control group increased only 2.6 share points."[548]

433. Endo structured the Opana ER savings cards so that they could be used by the same person for separate prescriptions in the same month.[549]

434. Endo also employed earlier versions of the Opana ER savings card that could be redeemed up to six times per card for up to $25 each[550]—making it attractive to diverters and abusers. Aside from increasing the number of times it could be used, Endo aggressively raised the maximum discount for Opana ER. Between March 2011 to March 2012, Endo's Opana ER savings card had a maximum discount of $100.[551] Endo also distributed later versions of the Opana ER savings card that could be used up to 12 times for a total savings of $300.[552]

---

545 ENDO-CHI_LIT-00546435 (slide 28 of 86) (stating "20% of [savings card] redemptions are for greater than 3 uses indicating increasing brand loyalty"); *see also*, ENDO-OR-CID-00078247 (Multiple Usage tab); ENDO-OR-CID-00277701 (showing 64% of patients who used savings card during studied period used it more than once.).

546 ENDO-OR-CID-00277720.

547 ENDO-OR-CID-00277718.

548 ENDO-OR-CID-00277707.

549 ENDO-OR-CID-01291065.

550 ENDO-CHI_LIT-00547149 (slide 10 of 13).

551 ENT000070745, -746.

552 ENDO-CHI_LIT-00537588.

435. Endo collected numerous pieces of sales data from the cards. For example, the company knew that most people who redeemed a savings card would use it two or more times[553] and that the cards were frequently used to help pay for large quantities of high-dose Opana ER prescriptions.[554]

436. Endo even used Opana *immediate release* savings cards "to gain Opana ER business" as shown by the excerpt from the Endo document below:[555]

437. Endo's savings cards were used disproportionately by Tennesseans to purchase expensive Opana ER prescriptions. Between March 2011 to March 2012, more savings cards were used for Opana ER prescriptions over $100 in Tennessee than in any other state in the country.[556]

438. Aside from expensive prescriptions, Tennessee had some of the highest redemptions of Endo savings cards in the country.[557] The East Knoxville and North Knoxville territory had some of the highest redemptions of Opana ER savings cards in the country from January 1, 2009 to December 15, 2010.[558]

439. Endo's savings cards served as vehicles for abuse and diversion of Opana ER in Tennessee. Endo knew or should have known that many of these prescriptions were highly unlikely to be consumed by a single patient and were most likely diverted. Tennessee providers

---

553 *See*, *e.g.*, ENDO-OR-CID-00078246, -247 (Multiple Usage tab).

554 ENDO-OR-CID-00880021 (Dosage Summary tab showing savings cards used to purchased high dose Opana ER 65.28% of the time); ENDO-OR-CID-00078247 (Dosage Summary tab).

555 ENDO-OR-CID-00463633.

556 ENDO-OR-CID-00277722.

557 ENDO-OR-CID-00465100; ENDO-OR-CID-00744984 (Redemption Density Map tab).

558 ENDO-OR-CID-00744984 (Prescriber Summary Pharma tab, Column N).

whose practices showed signs of abuse or diversion had high numbers of Opana ER savings card redemptions. For example, in a March 2010 report, Endo knew that 411 savings card redemptions were attributed to prescriptions written by Dr. Abdelrahman Mohamed in Tennessee.[559]

440. Endo's sales representatives also made calls to[560] pharmacies in Tennessee and used them as a source of information to track down high-prescribing health care providers as well as to identify new prescribers to call on, including problematic prescribers.

441. Endo ignored red flags for abuse or diversion at Tennessee pharmacies and continued to push Opana ER in sales calls. Before the official launch of Opana ER, Endo instructed its sales representatives to establish relationships with pharmacies in Tennessee that had extremely high dispensing rates of controlled substances to target in future sales calls for Opana ER.[561]

442. Endo conducted an "[o]utreach program to 5,000 OPANA ER with INTAC pharmacies with the objective of continuing to differentiate OPANA ER with INTAC and generic oxymorphone ER (as well as reminder regarding the voluntary returns program for the original formulation of OPANA ER)."[562]

443. Endo also connected individuals prescribed Opana ER with pharmacies that had inventories of the drug through a "Pharmacy Locator" service in which a patient could call a toll-free number "for immediate access of product availability." As part of the service, Endo stated

559 ENDO-OR-CID-00465100 (Prescriber Summary Specialty tab, Column N, Rows 7072-704).

560 ENDO-OR-CID-00715695 (FULL LIST FOR PERSONAL PROMO tab); ENDO-OR-CID-00303416 (listing decile 10 pharmacies); ENDO-OR-CID-00773150.

561 *See* ENDO-OPIOID_MDL-4907827, -935 to -938.

562 ENDO-OR-CID-00724032.

that "[i]f product is not available at the preferred pharmacy, the pharmacy locator service will proactively search until dosage and supply are located."[563]

444. The enormous number of Opana ER prescriptions written and filled in Tennessee, especially at high doses, has equated to a substantial number of Tennesseans who have become addicted to opioids. A 2015 published meta-analysis of 38 studies evaluating opioid misuse, abuse, and addiction in chronic pain patients found rates of addiction averaging between 8–12%,[564] though the actual percentage is most likely higher because of those misclassified as physically tolerant.

445. Most people addicted to opioids started with prescription painkillers. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), it is estimated that 221,000 (or 4.56%) of the 4,850,000 adults in Tennessee have used prescription opioids for non-medical purposes. Of these, it is estimated that, as of 2014, at least 69,100 were addicted to opioids and required treatment for opioid abuse and 151,900 had risky prescription opioid use.[565]

446. While rates and reports of abuse varied over time, Endo knew in 2011 that:

> [w]hen considering the number of prescriptions dispensed, past 30-day abuse of oxymorphone . . . was reported significantly more frequently than past 30-day abuse [of] the other three compounds (oxycodone, hydrocodone, and fentanyl)[.]

---

563 ENDO-OR-CID-00453345; *see also*, ENDO-OR-CID-00715641 (Accepted Pharmacy Jan 2012 tab, Accepted Pharmacy Dec 2011 tab, Accepted Pharmacy Nov 2011 tab, Inventory By State Oct. 2011, Inventory By State Sept 2011 tab, Inventory by State August 2011 tab, Inventory by State July 2011 tab, Inventory by State June 2011 tab, Inventory by State May 2011, and Inventory by State April 2011 tab).

564 Kevin E. Vowles, *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis*, PAIN, 569, 156:4 (Apr. 2015).

565 *Prescription for Success*, TENNESSEE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES, 4 (2014) *available at* https://www.tn.gov/content/dam/tn/mentalhealth/documents/Prescription_For_Success_Full_Report.pdf.

At the same time, Endo also knew that reports of Opana ER abuse based on the number of prescriptions dispensed was even higher than generic extended release oxymorphone, oxycodone, hydrocodone, and fentanyl.[566]

447. A substantial number of Tennesseans were addicted to Opana ER or to other opioids because of Opana ER, which is highly concentrated oxymorphone and has been popular among those suffering from opioid use disorder and opioid abusers.

448. The State and its political subdivisions have spent significant public resources on treatment, toxicology reports, law enforcement, corrections, intervention programs, drug courts, prosecution, probation, and child welfare related to opioids, including Opana ER, and more funds are desperately needed to address this ongoing public health crisis.

449. The State and its political subdivisions have also spent public resources on identifying, reporting, and attempting to remediate TTP and Hepatitis C contracted as a result of intravenous Opana ER use.

450. Opioid use, morbidity, and mortality have increased exponentially nationwide and across Tennessee in the years since Endo first began aggressively marketing extended release opioids for long-term use.

451. In 2016, Tennessee had 22,944 nonfatal overdoses, 15,001 of which were outpatient visits and 7,943 were inpatient stays.[567] In 2017, 6,879,698 opioid prescriptions were written in Tennessee and there were 1,268 opioid-related overdose deaths, equaling a rate of 19.3 deaths per 100,000 persons—*69 % higher than the national rate* of 13.3.[568]

---

566 ENDO-OR-CID-00000264.

567 https://www.tn.gov/health/health-program-areas/pdo/pdo/data-dashboard.html.

568 *Id.*; *see also*, *Tennessee Opioid Summary*, NATIONAL INSTITUTE ON DRUG ABUSE, *available at* https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/tennessee-opioid-summary.

452. The federal government's Substance Abuse and Mental Health Services Administration (SAMHSA) has stated that the number of individuals enrolled in substance use treatment in Tennessee has varied between 16,590 in 2011; 19,115 in 2012; 14,149 in 2013; and 22,445 in 2015.[569]

453. Similarly, SAMHSA has stated that the number of Tennesseans enrolled in an opioid treatment program and receiving Medication-Assisted Therapy (MAT), excluding those receiving MAT through a private physician, totaled 5,371 in 2011; 6,079 in 2012; 2,422 in 2013; 4,421 in 2015; 5,280 in 2016; and 6,561 in 2017.[570] Similarly, the number of individuals receiving the treatment drug, buprenorphine, at substance abuse facilities in Tennessee has climbed from 299 in 2011; 475 in 2012; 488 in 2013; 1,179 in 2015; to 1,217 in 2017.[571]

454. A significant number of Tennesseans still need treatment. In Tennessee, only about 10.6% of individuals aged 12 or older with illicit drug dependence or abuse received treatment within the year prior to being surveyed.[572]

455. The State's opioid epidemic has also had a negative impact on infants, children, the elderly, and families generally.

---

569 *Behavioral Health Barometer Tennessee, Vol. 4*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, 13 *available at* https://www.samhsa.gov/data/sites/default/files/Tennessee_BHBarometer_Volume_4.pdf (hereinafter *Behavioral Health Barometer Tennessee*).

570 *Behavioral Health Barometer Tennessee,* 13; *2016 State Profile – Tennessee*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, available at https://wwwdasis.samhsa.gov/webt/state_data/TN16.pdf.

571 *Behavioral Health Barometer Tennessee,* 14; 2017 *State Profile – Tennessee*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *available at* https://wwwdasis.samhsa.gov/webt/state_data/TN16.pdf.

572 K. Edwards, *Opioid Abuse in Tennessee*, TENNESSEE DEPARTMENT OF MENTAL HEALTH & SUBSTANCE ABUSE SERVICES (citing SAMHSA Center for Behavioral Health Statistics and Quality, 2014), p. 1, *available at* https://www.tn.gov/content/dam/tn/mentalhealth/documents/Opioid_Abuse_in_TN_July_2015.pdf.

456. Tennessee is sixth in the nation for rates of opioid-related hospital admissions among senior citizens. In 2005, 467 out of every 100,000 Tennesseans aged 65 and older spent time hospitalized from opioid related use. By 2015, that rate more than doubled to 1,055.[573]

457. Opioid use and misuse have increased the numbers of infants suffering from neonatal abstinence syndrome (NAS), a withdrawal syndrome that occurs in babies exposed to opioids in utero. The number of NAS cases attributable to prescription opioids has been disproportionately high in Tennessee. A 2015 NAS update prepared by the Tennessee Department of Health shows that "[w]hen categorized into mutually exclusive categories of exposure, 48.5% of cases were exposed to prescription drugs only, 26.8% were exposed only to illicit or diverted drugs, and 23.2% were exposed to a mix of prescription and illicit or diverted drugs."[574]

458. In Tennessee, the rate of NAS was *three times* the national average between 2009 and 2012 and has been more than *ten times* the national average in areas of East Tennessee.[575] In 2013 and 2014, Tennessee had NAS ratios of 25.5 and 28.5 per 1,000 live births respectively.[576]

459. Endo's unfair and deceptive opioid marketing has also wreaked havoc on the lives of children in Tennessee. Adolescent misuse of prescription opioids is particularly devastating because it is the time when many individuals, who develop opioid-use disorder, first misuse opioids. Endo's push for providers to prescribe more and more of its narcotics has given more young children access to them.

---

573 Anita Wadhwani, *Opioid-related Hospitalizations More than Triple for Tennessee Seniors*, THE TENNESSEAN, *available at* https://www.tennessean.com/story/news/2017/08/13/opioid-related-hospitalizations-more-than-triple-tennessee-seniors/545556001/ (citing the U.S. Agency for Healthcare Research and Quality).

574 A.M. Miller, *Neonatal Abstinence Syndrome Surveillance Annual Report 2015*, TENNESSEE DEPARTMENT OF HEALTH 5 (2015), *available at* https://www.tn.gov/content/dam/tn/health/documents/nas/NAS_Annual_report_2015_FINAL.pdf.

575 Paul Campbell, M.D., PhD, *Neonatal Abstinence Syndrome in East Tennessee: Characteristics and Risk Factors among Mothers and Infants in One Area of Appalachia*, J. HEALTH CARE POOR UNDERSERVED 1293-1408, 28(4) 2017.

576 *Id.*

460. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system. Children removed from their home as a result of parental substance abuse are likely to remain in foster care longer and have significantly lower rates of adoption. A higher rate of adoption indicates that children removed from their homes remain in foster care longer and are less likely to exit from foster care to reunite with biological parents. Children with parents that abuse opioids are also much more likely to then abuse opioids.

461. In July 2017, Endo pulled Opana ER from the market following a request by the FDA. But because of the enduring fallout from addiction and other long-term consequences of Endo's conduct over the 11 preceding years since the Opana ER launch in 2006, the nuisance that Endo substantially helped to create continues and substantial equitable costs of abating the nuisance remain.

III. VIOLATIONS OF THE LAW

COUNT I: TENNESSEE CONSUMER PROTECTION ACT
Tenn. Code Ann. §§ 47-18-104(a) and (b)

462. Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1–461 of this Complaint.

463. Endo's advertising, promotion, and offering of its opioid products, as alleged herein, constitutes "trade," "commerce," and/or a "consumer transaction" as defined in Tenn. Code Ann. § 47-18-103(19) and as those terms have been interpreted by the Tennessee Supreme Court in *Fayne v. Vincent*, 301 S.W.3d 162, 175 (Tenn. 2009) and elsewhere.

464. As used in this Complaint, "unsubstantiated" means not possessing competent and reliable scientific evidence, defined as tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in

an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results, at the time a claim is made. In the alternative, the State submits that "unsubstantiated" means not possessing substantial evidence, defined as adequate and well-controlled investigations, at the time a claim is made. The State submits that as applied there is no difference between the standards and that, regardless, Endo's unsubstantiated claims as referenced in this Complaint fail either standard.

465. By engaging in any act or practice that causes or tends to cause a consumer or any other person to believe what is false or that misleads or tends to mislead a consumer or any other person as to a matter of fact, Endo has violated Tenn. Code Ann. § 47-18-104(b)(27).

466. By expressly or implicitly claiming that Opana ER acted as an abuse deterrent drug, had abuse deterrent properties, remained intact, was crush resistant, could not be crushed, could not be liquefied, was otherwise resistant to abuse, or was less abusable than other opioids or drugs when this was not the case or when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

467. By stating that Endo had pulled its original formulation of Opana ER from the market due to safety concerns when this was not the case, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

468. By expressly referencing pseudoaddiction in its marketing or through words or phrases of similar import when this claim was deceptive or unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

469. By expressly or implicitly claiming that an addiction mitigation tool including a patient contract, patient diary, patient self-report, urine drug screen, opioid risk tool, or other tool

is more effective than it actually is or when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

470. By expressly or implicitly claiming that Opana ER produced less euphoria compared to other opioids, produced fewer peaks and valleys that led to feelings of euphoria compared to other opioids, or was less likely to be abused because a patient experienced less euphoria than compared to other opioids or through words or phrases of similar import when this was not the case or when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

471. By expressly or implicitly understating the risk of addiction including, without limitation, claims that Opana ER or its other opioids had a low risk of addiction or habituation, improved efficacy with less tolerance, or otherwise had less potential for addiction, when this was not the case or when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

472. By expressly stating that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

473. By making claims about higher doses of its opioid products and failing to disclose the increased risk of addiction and other serious risks or side effects from higher doses of its opioid products, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

474. By promoting its opioids for long-term use and failing to disclose the lack of evidence supporting long-term use of its opioids, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

475. By expressly or implicitly claiming without qualification that its opioid products were safer than they actually were, had minimal side effects, less risk of narcotic-related problematic and concerning side effects, or otherwise overstating the safety of its opioid products when this was not the case or when this claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

476. By expressly or implicitly claiming that Opana ER was safer, more effective, as effective, or superior to OxyContin, Avinza, Kadian, or other opioids, when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

477. By expressly or implicitly claiming that the reformulated Opana ER was safer, more effective, or superior to generic oxymorphone extended release formulations when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), (b)(8), and (b)(27) in each instance.

478. By expressly or implicitly representing that its opioid products improve a patient's quality of life or through words or phrases of similar import when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

479. By expressly or implicitly representing that its opioid products improve a patient's function or through words or phrases of similar import when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

480. By expressly or implicitly representing that its opioid products act as a sleep aid or through words or phrases of similar import when this was not the case or when the claim was

unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

481. By expressly or implicitly representing that its opioid products improve emotional well-being or self-esteem or through words or phrases of similar import when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

482. By expressly or implicitly representing that its opioid products improve or help work productivity or through words or phrases of similar import when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

483. By expressly or implicitly representing that its opioid products improve or help concentration or through words or phrases of similar import when this was not the case or when the claim was unsubstantiated at the time made, Endo has violated Tenn. Code Ann. § 47-18-104(a), (b)(5), and (b)(27) in each instance.

484. By expressly or implicitly representing that Opana ER and its other opioids were safe when taken by the elderly without disclosing the increased risk of respiratory depression, death, and other serious health risks, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

485. By referring in its marketing to recommendations or promotional, policy, educational, and other materials from the American Pain Society, the American Geriatric Society, the American Academy of Pain Medicine, the American Pain Foundation, or other third-party pain advocacy groups Endo substantially funded without disclosing this financial connection, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(27) in each instance.

486. By making sales calls to providers after knowing of credible indicators of abuse or diversion of opioids, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(43)(C) in each instance.

487. By making sales calls to pharmacies after knowing of credible indicators of abuse or diversion of opioids, Endo has violated Tenn. Code Ann. § 47-18-104(a) and (b)(43)(C) in each instance.

488. By engaging in the above material misrepresentations and omissions concerning Opana ER, a pharmaceutical drug that affects consumer health and safety, Endo has caused or is likely to cause substantial injury to consumers which, due to the complex subject matter and consumer deference to health care providers, is not reasonably avoidable by consumers and not outweighed by countervailing benefits to consumers or competition, and thus has violated Tenn. Code Ann. § 47-18-104(a) in each instance.

COUNT II: COMMON LAW NUISANCE

489. Plaintiff, the State of Tennessee, incorporates by reference and re-alleges each and every allegation contained in paragraphs 1–461 of this Complaint.

490. Through the actions described above, Endo has contributed to and/or assisted in creating and maintaining a condition that has interfered with public health, endangered the lives and health of Tennessee residents, and interfered with the operation of the commercial market.

491. Endo had a duty under the TCPA to disseminate non-misleading marketing materials, had a duty under the TCPA to disclose material facts, had a duty not to indirectly offer or sell an unlawful product, and had a duty not to participate in abuse or diversion of controlled substances. Endo violated each of these duties in Tennessee.

492. While Endo's degree of care is not relevant in a common law nuisance suit brought by the sovereign State, Endo behaved negligently, recklessly, or intentionally as set forth above.

493. Through the actions described above, Endo has contributed to and/or assisted in creating and maintaining a condition that endangers the life or health of Tennessee residents and that unreasonably interferes with or obstructs rights common to the public.

494. While Endo marketed Opana ER and thereafter, opioid use, abuse, addiction, and overdose deaths have increased throughout Tennessee. Locations such as the offices of high-prescribing health care providers and the pharmacies at which their patients fill opioid prescriptions have attracted drug dealers and those addicted to opioids.

495. The greater demand for emergency services, law enforcement, addiction treatment, children's services, foster care, and other social services places an unreasonable burden on governmental resources including the State and its political subdivisions.

496. Endo expanding the market for prescription opioids in Tennessee by making misrepresentations and omissions to health care providers, especially to general practitioners, nurse practitioners, and physician assistants, as well as targeting providers and pharmacies with practices that had actual, or signs indicative of, abuse or diversion, has created an overabundance of opioids available for criminal use and fueled a wave of addiction, abuse, injury, and death.

497. Endo's actions described above were a substantial factor in opioids becoming widely available, used, and all too often abused.

498. But for Endo's actions, opioid use would not have become so widespread in Tennessee, and the enormous public health hazard of opioid overuse, abuse, and addiction that now exists could have been averted or mitigated. Endo's actions have and will continue to injure and harm many residents throughout Tennessee.

499. While tort-based standards are not applicable to a public nuisance suit brought by the sovereign State, the public nuisance and associated financial and economic losses were foreseeable to Endo, which knew or should have known that its unfair and deceptive business practices regarding the safety, purported benefits, and comparative superiority or equivalency of its opioid products, its continued sales targeting of providers and pharmacies with practices that had actual, or signs indicative of, abuse or diversion of opioids, and its other conduct described herein were creating a public nuisance.

500. Endo intended health care providers in Tennessee to prescribe its extended release opioids for long-term use and for patients to fill those prescriptions and to keep filling those prescriptions at higher and higher doses. A reasonable person in Endo's position would foresee not only an expanded market, but the other likely and foreseeable results of Endo's conduct—the widespread problems of opioid addiction and abuse, particularly given the easy manipulation of its original and reformulated Opana ER and the drug's popularity among opioid abusers and those addicted in Tennessee.

501. Endo was on notice and aware of signs both that Tennessee health care providers were prescribing unreasonably high numbers of opioids and that the broader use of opioids in Tennessee were causing the kinds of harm described in this Complaint.

502. Endo's business practices generated a new and very profitable circular market in Tennessee with the promotion of opioids—providing both the profitable supply of narcotics to prescribe and sell, as well as causing addiction which fueled the demand to buy more.

503. Endo acted without express authority of a statute in misrepresenting the safety, comparative superiority or equivalence of its opioids to other products, and benefits of its opioid

products, failing to disclose the increased risk of addiction at higher doses, and failing to disclose the lack of substantiation for long-term use of opioids among other conduct.

504. The health and safety of Tennessee residents, including those who use, have used, or will use opioids, as well as those affected by abusers of opioids, is a matter of great public interest and of legitimate concern to the State. Tennesseans have a right to be free from conduct that endangers their health and safety and that interferes with the commercial marketplace. Endo's conduct interfered in the enjoyment of these public rights.

505. As part of its nuisance action, the State does not seek any damages attributable to TennCare, Medicaid, or Medicare.

506. Through this action, the State does not seek removal of any opioid product from the market and does not seek recovery for personal injury, death, or property damage.

IV. PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff, the State of Tennessee, *ex rel.* Herbert H. Slatery III, Attorney General and Reporter, pursuant to the TCPA, the Attorney General's general statutory authority, the Attorney General's authority at common law, and this Court's equitable powers, prays:

1. That this Complaint be filed without cost bond as provided by Tenn. Code Ann. §§ 20-13-101 and 47-18-116;

2. That process issue and be served upon Endo requiring it to appear and answer;

3. That this Court adjudge and decree that Endo has engaged in the aforementioned acts or practices that violate the TCPA;

4. That pursuant to Tenn. Code Ann. § 47-18-108(a)(1), (a)(4), and (a)(5), this Court permanently enjoin and restrain Endo from engaging in the aforementioned acts or practices which violate the TCPA;

5. That the Court find that Endo has made the material misrepresentations and omissions set forth above, that the misrepresentations and omissions were widely-disseminated in Tennessee, and that Endo's opioid products were purchased in Tennessee;

6. That pursuant to Tenn. Code Ann. § 47-18-108(b)(1), this Court make such orders or render such judgments as may be necessary to restore to any person, as defined in Tenn. Code Ann. § 47-18-103(13), who has suffered any ascertainable loss, as defined in Tenn. Code Ann. § 47-18-2102(1), including statutory interest, and requiring that Endo pay all costs of distributing and administering the same, including through the use of third-party administrator;

7. That this Court make such orders or render such judgments as may be necessary to disgorge the profits and ill-gotten gains Endo realized by reason of the alleged violations of the TCPA;

8. That this Court adjudge and decree that Endo pays a civil penalty of $1,000 to the State for each violation of the TCPA, as provided by Tenn. Code Ann. § 47-18-108(b)(3);

9. That apart from any civil penalties referenced above and pursuant to Tenn. Code Ann. § 47-18-125, this Court adjudge and decree that Endo pays a civil penalty of $10,000 per violation for any method, act, or practice that violates the TCPA that the Court finds Endo knowingly, as defined in Tenn. Code Ann. § 47-18-103(10), used which targeted elderly persons, with each violation constituting each misrepresentation or deceptive statement that appeared on a solicitation or advertisement;

10. That this Court enter judgment against Endo and in favor of the State for the reasonable costs and expenses of the investigation and prosecution of this action, including attorneys' fees, costs and expert and other witness fees, as provided by Tenn. Code Ann. § 47-18-108(a)(5) and (b)(4), and other state law;

11. That an order be entered that provides for abatement of the public nuisance Endo has created, the equitable costs of abating this nuisance, an award to the State for damages in an amount to be determined at trial, and any other relief or remedy allowable under state law;

12. That all costs, including discretionary costs, in this case be taxed against Endo;

13. That a jury be empaneled to hear and decide all appropriate matters; and

14. That this Court grant the State such other and further relief as this Court deems just and proper.

Respectfully submitted,

HERBERT H. SLATERY III, B.P.R. NO. 9077
Attorney General and Reporter

BRANT HARRELL, B.P.R. No. 24470
Senior Assistant Attorney General
MARGARET ROWLAND, B.P.R. No. 33513
Assistant Attorney General
OLHA RYBAKOFF, B.P.R. No. 24254
Senior Assistant Attorney General
CAROLYN U. SMITH, B.P.R. No. 17166
Senior Assistant Attorney General
Office of the Attorney General of Tennessee
Consumer Protection Division
P.O. Box. 20207
Nashville, TN 37202
(615) 741-3549

(615) 532-2910 (fax)
brant.harrell@ag.tn.gov
olha.rybakoff@ag.tn.gov
margaret.rowland@ag.tn.gov
carolyn.smith@ag.tn.gov

[Signature Page Endo Complaint]

GLOSSARY OF TERMS

AAPM – American Academy of Pain Medicine;

ANDA – acronym for the FDA's Abbreviated New Drug Application, used by generic manufacturers;

APF – American Pain Foundation;

APS – American Pain Society;

ASI-MV— Addiction Severity Index-Multimedia Version;

ATC – around-the-clock;

CII or C2 – controlled substance under Schedule II of the Controlled Substances Act;

COMM – acronym for the mitigation tool "Current Opioid Misuse Measure;"

CYP – acronym for cytochrome p450, an enzyme in the human body;

HCPs – health care providers;

KOLs – key opinion leaders;

LA – long-acting;

NAVIPPRO – acronym for National Addictions Vigilance Intervention & Prevention Program, an opioid abuse surveillance program;

NDA –acronym for the FDA's New Drug Application;

NSAIDs – non-steroidal anti-inflammatory drugs;

OPDP – acronym for the FDA's Office of Prescription Drug Promotion;

PCP – primary care physician;

PDE – acronym for primary detail equivalent; another term for promotional sales call;

Q12h – once every 12 hours;

SA – short-acting;

sNDA – acronym for the FDA's Supplemental New Drug Application; and

SOAPP – acronym for the mitigation tool "Screener and Opioid Assessment for Patients with Pain."