

# A Prescription Drug Illegal Marketing Case:

“Dead Baby” Messaging, a Billion-Dollar “Product Hop” & the Buprenorphine Public Health Campaign That Wasn’t

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# Disclosures / COI

## **False Claims Act relator:**

DOJ vs. Reckitt Benckiser Pharmaceuticals (2019)

DOJ vs. Indivior (2020)

**Fact witness:** federal Purdue Pharma investigation

**Sales rep:** RBP/Indivior (2005-2012)

Purdue Pharma (2003-2004, 2014-2016)

**Disclaimer:** Financial settlement w/RB Group & Indivior:

No finding or admission of wrongdoing or liability. Expressly denied all claims & allegations of retaliation

Not directly employed by RB Group (employed by Reckitt Benckiser Pharmaceutical Inc, which became Indivior in 2014 )

# Abstract Presentation Objectives:

1. Analyze 1<sup>st</sup> illegal pharma marketing case - addiction medicine -- alleged anticompetitive actions from 2009-14
2. Gain insights: regulatory gaps, ethics/ equity, industry tactics, policy implications

## Methods:

Case study & policy synthesis +analysis.

**Data collection:** legal, regulatory & publicly available pharmaceutical industry documents, academic literature, media reports /// auto-ethnographic data

# Public health breakthrough

## DATA 2000 → Office-based buprenorphine

### Paradigm shifts

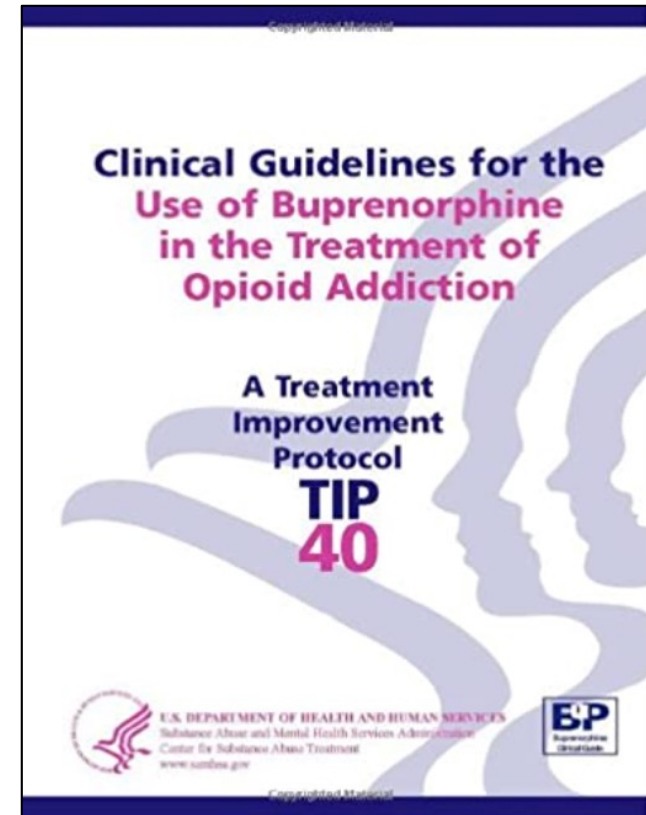
ACCESS: equity & capacity

### Pharma Marketing goals:

ACCESS:  market share /profits  
 metrics: prescribers/RXs

- formulary & reimbursement
- regulations /regulators
- market exclusivity

"Clinical Liaisons" – trusted advisors



# Implementing a Product hop: Public health claims & “Mission Protect”

Maintaining Market Share

1. Pricing changes
2. Regulatory strategies
3. Marketing changes: “Mission Protect”

Child poisoning -- “dead baby” sales story

“DISC: Diversion, Interactions, Safety, Children”

False public health superiority claims

DEA audit “scare tactics”

Altered/ misleading use of poisoning center research

# Implementing a Product Hop: Exploiting Regulatory Weaknesses



The NEW ENGLAND  
JOURNAL of MEDICINE

Feb. 6, 2020

## Abuses of FDA Regulatory Procedures — The Case of Suboxone

Rebecca L. Haffajee, J.D., Ph.D., M.P.H., and Richard G. Frank, Ph.D.

- Orphan drug designation (2002) - 7 years exclusivity
- 2012 Product hop – “hard switch” tablets to film
- “sham” citizen petition to FDA
- REMS data sharing/ obstruction- delay generics
- 9 month delay worth ~ \$1 billion sales

(2020, Haffajee & Frank)

FEBRUARY 1, 2013

# Novel Tactics Impede Generic Competition to Suboxone Tablets

*Health Letter, February 2013*

- Rocky Mountain Poison and Drug Center (RMPDC) data – commissioned to support pediatric safety /public health claims
- Abruptly discontinuing tablet
- “conversion” to Film formulation success – 70% by Sept.2012 (eventually 85% /industry record)
- “patients paying monopoly prices”

# No evidence of superiority- new formulation vs. old formulation

## **Oct. 2009: Manufacturer letter to FDA:**

Can we promote public health benefits of Film packaging?

## **March 2010: FDA response:**

**NO** on pediatric safety. No comment on diversion (ask DEA)

## **Nevertheless, DOJ indictment quotes CEO :**

“We will be making the most of every minute between now & generic approval to convert our tablet business to film,’ including a ‘Full Blitz campaign for salesforce’

*... to raise ‘diversion and misuse and pediatric safety’ in sales presentations to physicians.”*



# False public health claims

## **Misleading sales charts:**

“Helping to Reduce Pediatric Exposure”

“Associated with Reduced Rates of Diversion & Abuse”

- omitted relevant study results

**Citizen Petition to FDA** , Sept. 25, 2012

company executives altered 5-page study summary

## **Public announcement / Patient & Prescriber letters**

“ The decision to take Suboxone Tablets off the market was a voluntary choice

**as a result of recent information the company received showing higher rates of accidental pediatric exposure”**

# Ethical lapses: industry & clinician relationships

Par.	Date	State	Sent by	False and Fraudulent Statement and Representation
91	5/17/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Op-Ed Letter to The Boston Globe, The Boston Herald, and The Patriot Ledger: Suboxone Film was “preventing diversion, recidivism, and the accidental death of inquisitive children,” and by declining to provide Medicaid coverage of Suboxone Film, MassHealth officials were “engaging in 21st century biological warfare, no different than giving small pox infected blankets to the Indians”
93	6/23/2011	MA	Physician, at direction of INDIVIOR Gov. Mgrs.	Email to MassHealth officials: “there is less opportunity for diversion with” Suboxone Film, “there is less chance that a curious child will ingest the film,” and “the inaction by the policy makers of MassHealth can be seen just as Strom Thurmond’s filibuster in opposition of the Civil Rights Act of 1957.” Physician subsequently emailed INDIVIOR Gov. Mgrs. requesting that INDIVIOR donate \$30,000 to his foundation and give him a Harley-Davidson Road King motorcycle as payment

# Industry Speaker program example: DEA “scare tactic”

*“They all spoke about the DEA audits & Dr C. shared his experience with the others as he is the only one at the table that experienced a [DEA] visit. They spoke about the fear of loosing [sic] Schedule III status.*

*Dr F. said then clearly putting all patients on the Film is the best way to protect our ability to continue to care for patients.”*

-- RBP Sales representative report to manager, Nov. 9, 2010

# “Baby death articles”

71	12/5/2011	IL, IN, KY, MI, OH, TN, WV	INDIVIOR sales representative collected “best practices” for convincing doctors, pharmacists, and others to switch patients to Suboxone Film from others across the region, including “Baby Death articles;” “Diversion with Tablets and high street value of \$25.00 per pill;” “Film harder to sell on streets;” “if patients call office and ask if doctor writes the tablets (or pills) that is a patient you do not want—they will be diverting and your office can or will be tied to that illicit drug;” “I inform my doctors (and pharmacists) that insurance companies are beginning to view the film the same way we do . . . as the superior (safer) product;” “I focus on the
68	9/2/2011	MD	INDIVIOR-paid speaker told physicians that Suboxone Film was “preventing pediatric death in graphic terms”
69	10/26/2011	TN	INDIVIOR sales representative “led physicians to the internet so that they may see how their decisions to prescribe any tablet over [Suboxone Film] may have a negative impact on the community. There are current articles that [the tablet] kills children all over the internet and this helps them to see the reasons to prescribe [Suboxone Film] over the tablets. . . . One of my doctors . . . still has not converted all of his patients to [Suboxone Film]. He was able to visit the internet article to see how [Suboxone Film] could put safe guards in the community as well
62	7/7/2011	NC	INDIVIOR sales representative met with a physician who was “still giving [some] patients the choice between the Suboxone Film and tablet . . . . I strongly encouraged [the physician] to protect herself, her practice and her medical license by prescribing Suboxone film to ALL of her patients. I said, ‘I don’t want any of my physicians to find themselves on a witness stand defending their decision for prescribing Suboxone tablets which caused the death of a child.’ Hopefully that statement convinced [the physician] to adopt a fail first policy on the Suboxone film”



THE UNITED STATES  
DEPARTMENT *of* JUSTICE

July 11, 2019

**Department of Justice Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery Concerning Opioid Drug in U.S. History**

July 24, 2020

**Indivior Solutions Pleads Guilty to Felony...  
Indivior Entities Pay \$600 Million to Resolve Criminal & Civil Investigations**

# Settlements

## **Reckitt Benckiser Group**

Settled (without liability) -- promoting Suboxone™ for “unsafe, ineffective, & medically unnecessary” uses

## **Indivior**

Guilty pleas -- Subsidiary - Indivior Solutions - felony

- CEO & Medical Director – misdemeanors /fines / JAIL
- Settled 3 key allegations

**\$10 million payment paid to FTC** for patient refunds

+ compliance reporting + req's

# Public health harms

## **Anti-competitive behavior /illegal marketing**

- Artificially higher cost of treatment
- cost impact & equity -- “two tiers” of treatment  
increased # cash clinics /racialized access  
(Hansen, Roberts, Netherland, 2012; Van Zee & Fiellin, 2019)
- Reputation /trust re: office-based  
treatment /buprenorphine
- negative publicity, stigma

# Policy levers (efficacy /deterrence unknown)

- Regulatory changes – patents, FDA, FTC
- Increased enforcement/ penalties
- Civil litigation / Criminal charges
- Marketing: sunshine laws /disclosure
- *PharmedOut approach to industry* - “no free lunch”
- Occupational licensing -- pharma sales reps-



# Citations

- Carrier, M.A. & Shadowen, S.L. (2016) Product Hopping: A New Framework, *Notre Dame Law Review* 92 (1) 167–230.
- Haffajee, R. L., & Frank, R. G. (2020). Abuses of FDA Regulatory Procedures—The Case of Suboxone. *New England Journal of Medicine*, 382(6), 496–498.  
<https://doi.org/10.1056/NEJMp1906680>
- Hansen Helena & Roberts Samuel K. (2012). Two Tiers of Biomedicalization: Methadone, Buprenorphine, and the Racial Politics of Addiction Treatment. In Julie Netherland (Ed.), *Critical Perspectives on Addiction* (Vol. 14, pp. 79–102). Emerald Group Publishing [https://doi.org/10.1108/S1057-6290\(2012\)0000014008](https://doi.org/10.1108/S1057-6290(2012)0000014008)
- Netherland, J. C. (2011). Becoming Normal: The Social Construction of Buprenorphine and New Attempts to Medicalize Addiction. 288, dissertation.
- Oldani, M. J. (2004). Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices. *Medical Anthropology Quarterly*, 18(3), 325–356.  
<https://doi.org/10.1525/maq.2004.18.3.325>
- Novel Tactics Impede Generic Competition to Suboxone Tablets. (2013). *Public Citizen Health Letter*. <https://www.citizen.org/news/novel-tactics-impede-generic-competition-to-suboxone-tablets/>

# Citations

- Mulinari, S. (2016). Unhealthy marketing of pharmaceutical products: An international public health concern. *Journal of Public Health Policy*, 37(2), 149–159. <https://doi.org/10.1057/jphp.2016.6>
- Santoro, M., & Gorrie, T. M. (2015). *Ethics and the Pharmaceutical Industry*. Cambridge University Press.
- Van Zee, A., & Fiellin, D. A. (2019). Proliferation of Cash-Only Buprenorphine Treatment Clinics: A Threat to the Nation’s Response to the Opioid Crisis. *American Journal of Public Health*, 109(3), 393–394. <https://doi.org/10.2105/AJPH.2018.304899>
- USA vs Indivior, Inc. (a/k/a Reckitt Benckiser Pharmaceuticals Inc) and Indivior PLC, Superseding Indictment, 1:19-cr-00016 (U.S. District Court for the Western District of Virginia August 14, 2019)
- U.S. Department of Justice (DOJ). (2019). *Justice Department Obtains \$1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History*. DOJ Office of Public Affairs; Press Release 19-749.
- U.S. Department of Justice (DOJ), (2020a). *Indivior Solutions Pleads Guilty To Felony Charge & Indivior Entities Agree To Pay \$600 Million To Resolve Criminal & Civil Investigations As Part Of DOJ’s Largest Opioid Resolution*. The Department of Justice (DOJ) Office of Public Affairs; Press Release 20-697.

Questions?

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