

ABSTRACT Title: *A Prescription Drug Illegal Marketing Case: “Dead Baby” Messaging, a Billion-Dollar “Product Hop” and the Buprenorphine Public Health Campaign That Wasn’t*

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Background: The 2002 approval of buprenorphine/naloxone (Suboxone™) was groundbreaking for public health.

- 1) first office-based opioid use disorder treatment.
- 2) first block-buster addiction medicine (\$1 billion/annual sales).

But the manufacturer used illegal tactics to deter generic competition, and extend its market dominance and profits. A decade later, a subsidiary pled guilty criminally, two executives went to jail, and the company and its parent group paid a record \$2 billion total settlement.

Objective: Analyze the first illegal marketing case to be prosecuted against an addiction medicine company, focusing on the alleged anticompetitive actions from 2009-14. Gain insights to regulatory gaps, ethical lapses, industry tactics, and policy implications.

Methods: Case study. Analyze and synthesis data from legal, regulatory, and industry documents, government hearings, and academic literature, informed by auto-ethnographic data.

Results: A multi-pronged company strategy coerced patients and doctors to switch to a new formulation through a false public health "sales story." pricing changes, and other tactics. A disingenuous FDA citizen petition sought to further delay generic market entry. Sales messages included “dead baby” child poisoning stories, and false public health superiority claims.

The manufacturer was willing to cannibalize sales of its buprenorphine tablets to further force a “hard switch” to the new Film product— resulting in an anti-competitive "product hop."

Examples of ethical lapses extended outside of the company: Addiction physicians were recruited by company sales reps and medical liaisons to influence insurance formulary coverage (especially Medicaid). One example: legal documents quote a Massachusetts doctor requesting gifts from the manufacturer as payment, including a Harley Davidson motorcycle and donation to his foundation.

Conclusions: The buprenorphine product hop was among the most successful in pharma history (85% market share). The artificially higher cost, for an effective treatment in the midst of an opioid overdose crisis, harmed patients, plans, and tax payers. The reputation of office-based treatment with buprenorphine was impacted as well, due to negative publicity and stigma resulting from the illegal marketing case, a true public health loss.

Policy changes have been proposed, but may be difficult to implement. Criminal charges and financial penalties provide unknown efficacy for deterrence.

CITATIONS:

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COI: Indivior/ Reckitt Benckiser Group

Other: I participated in legal settlements: 1) from the DOJ & states (as relator /whistleblower re: civil/criminal cases, per the False Claims Act) & 2) wrongful discharge/employment settlements by Indivior & RB Group.

