The Potency Arms Race: Generic Manufacturer Product-Line Expansion and the Geography of Opioid Strength

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Abstract

Between 2006 and 2010, the number of distinct oxycodone products in the United States nearly tripled—yet the economics literature treats generic opioid supply as a homogeneous volume problem. I show that generic manufacturers competed on *potency*, not price. Using 178 million DEA ARCOS transactions, I exploit Mallinckrodt Pharmaceuticals' 2008 launch of high-dose oxycodone (20mg, 40mg, 80mg) as a shift-share instrument: counties with higher pre-period Mallinckrodt distribution exposure received disproportionately more potent pills. The first stage is strong ($\hat{\beta} = 3.97$, 55/55 states same sign) and passes a hydrocodone placebo test ($p = 0.48$). A one-standard-deviation increase in 2006 Mallinckrodt share raised county oxycodone potency by 0.14 standard deviations—a moderate, policy-relevant effect driven entirely by the 20–30mg dose range. Standard industrial organization dynamics in the generic drug market—product variety competition without abuse-deterrent regulation—shaped the geographic potency of the opioid crisis.

JEL Codes: I18, L11, L65, K32

Keywords: opioid crisis, generic pharmaceuticals, product variety, potency, shift-share

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1. Introduction

The American opioid crisis killed over 500,000 people between 1999 and 2020, with prescription opioids responsible for the first and deadliest wave (Case and Deaton, 2015, 2017). A large and growing economics literature has identified the supply-side drivers of this epidemic: aggressive physician detailing by Purdue Pharma (Alpert et al., 2022), lax state prescribing regulations (Buchmueller and Carey, 2018), pharmacy dispensing incentives (Eichmeyer and Zhang, 2022), and the moral hazard of insurance coverage for opioids (Powell et al., 2020). Yet all of this work treats the generic opioid supply chain as if it delivered a homogeneous product. A pill is a pill is a pill.

This paper shows that a pill is decidedly not a pill. Between 2006 and 2010, the number of distinct oxycodone products (unique manufacturer-strength combinations) in the United States nearly tripled, from 226 to 643. Generic manufacturers entered the market not by undercutting branded prices—the standard Hatch-Waxman story—but by launching *higher-dose* formulations that delivered more morphine-equivalent milligrams per tablet. This "potency arms race" was invisible in aggregate pill counts but profoundly reshaped the geographic distribution of opioid strength.

The central empirical challenge is that county-level potency is endogenous: communities with higher addiction rates may attract more potent prescriptions. I address this with a shift-share instrument that exploits a single, precisely timed corporate event. In 2007–2008, Mallinckrodt Pharmaceuticals—then the largest generic oxycodone manufacturer by volume—expanded its product line from 5 to 9 dose strengths, adding 20mg, 40mg, and 80mg immediate-release tablets. This was a corporate headquarters decision driven by competitive strategy in the generic market, not by county-level demand conditions. The instrument interacts each county's 2006 Mallinckrodt distribution share (determined by pre-existing distributor-manufacturer logistics relationships) with this national product expansion.

The first stage is strong and remarkably stable. Counties with a one-percentage-point higher 2006 Mallinckrodt share experienced a 3.97 MME/pill larger increase in oxycodone potency between the pre-expansion (2006–2007) and post-expansion (2009–2010) periods, controlling for state fixed effects. In a leave-one-state-out exercise, all 55 state-drops yield positive coefficients ranging from 3.57 to 4.24—exceeding the stability benchmark in Young (2022). An event study using the county-year panel confirms the identifying assumption: the interaction is flat in the pre-period (2006 relative to the 2007 base year) and increases monotonically from 2008 through 2012, with coefficients of 2.68, 3.98, 6.30, 8.51, and 9.42 in successive post-expansion years.

A hydrocodone placebo test provides the key falsification. Mallinckrodt did *not* expand

its hydrocodone product line during this period. If the instrument captures county-specific demand shocks rather than supply-side product exposure, it should predict hydrocodone potency changes as well. It does not: the placebo coefficient is -0.035 ($p = 0.48$), an order of magnitude smaller than the oxycodone first stage. The potency escalation was specific to the drug whose product variety expanded.

The standardized effect size is 0.14—a moderate, policy-relevant magnitude. To translate: a county moving from the 25th to the 75th percentile of 2006 Mallinckrodt exposure experienced roughly 0.7 additional MME per oxycodone pill, equivalent to one extra 5mg tablet's worth of morphine equivalent for every seven pills dispensed. The effect is concentrated in the 20–30mg dose range (the commercially relevant expansion) and is larger in high-volume counties (SDE = 0.18) where distributor relationships most strongly channeled the new products.

This paper contributes to three literatures. First, it advances the economics of the opioid crisis by documenting a new supply-side channel—generic product variety competition—that the existing literature has overlooked. While Alpert et al. (2022) trace the role of OxyContin marketing and Ruhm (2019) decompose aggregate overdose trends, no prior work has examined how generic manufacturers' portfolio decisions shaped the *potency* composition of local opioid supply. Second, it contributes to industrial organization by showing that generic pharmaceutical competition can operate on the product-variety margin rather than the price margin, with public health externalities that Hatch-Waxman's regulatory framework was not designed to address. Third, it contributes to the shift-share instrument literature (Borusyak et al., 2022; Goldsmith-Pinkham et al., 2020) by constructing an instrument from a single, identifiable corporate event—Mallinckrodt's product expansion—where the timing, motivation, and product-level details are all observable.

The paper proceeds as follows. Section 2 describes the institutional setting. Section 3 presents the data. Section 4 develops the empirical strategy. Section 5 reports results and robustness checks. Section 6 concludes.

2. Institutional Background

The generic oxycodone market, 2006–2012. Oxycodone is a Schedule II controlled substance and the active ingredient in both branded OxyContin (extended-release, manufactured by Purdue Pharma) and dozens of generic immediate-release formulations. The generic market expanded rapidly after key Purdue patents expired, with the number of distinct oxycodone NDC codes (National Drug Codes, each representing a unique manufacturer-strength-formulation combination) rising from 226 in 2006 to 643 by 2010. By 2009, generic

manufacturers collectively shipped more oxycodone pills than Purdue.

Mallinckrodt's product-line expansion. Mallinckrodt Pharmaceuticals (later acquired by Covidien, then Medtronic, and re-spun as Mallinckrodt plc) was the largest generic oxycodone manufacturer by volume in 2006, shipping over 1 billion pills annually. In 2006, Mallinckrodt offered oxycodone in 5 dose strengths: 5mg, 7.5mg, 10mg, 15mg, and 30mg. In 2007, it added a 2.5mg formulation. Then in 2008, Mallinckrodt launched three high-dose immediate-release tablets: 20mg, 40mg, and 80mg. This expansion nearly doubled Mallinckrodt's product count and pushed its average MME per pill from 9.3 in 2006 to 14.6 in 2008 and 18.0 in 2009.

The high-dose products competed directly with Purdue's OxyContin, which dominated the ≥20mg oxycodone market. Unlike OxyContin, Mallinckrodt's immediate-release formulations lacked abuse-deterrent properties, making them both cheaper and easier to abuse. The high-dose share of Mallinckrodt's oxycodone MME (pills ≥20mg weighted by dose strength) rose from 7.8% in 2006 to 54.4% in 2009.

Distribution networks and geographic exposure. Opioid pills travel from manufacturers to wholesale distributors (McKesson, Cardinal Health, AmerisourceBergen, and dozens of smaller firms) to retail pharmacies. Distributor-manufacturer relationships are sticky: pharmacies contract with specific distributors, and distributors maintain purchasing relationships with specific manufacturers based on volume discounts, logistics, and historical ties. A county's exposure to any given manufacturer's products is therefore substantially determined by which distributors serve that county and which manufacturers those distributors purchase from—a supply-chain geography that predates any particular product launch.

3. Data

DEA ARCOS. The primary data source is the Drug Enforcement Administration's Automation of Reports and Consolidated Orders System (ARCOS), which records every shipment of every Schedule II and III controlled substance in the United States. The full database, released publicly following litigation by *The Washington Post* and HD Media (Higham et al., 2019), contains 178 million transactions from 2006 to 2012. Each record identifies the manufacturer (`Revised_Company_Name`), distributor (`Reporter_family`), destination county (`BUYER_STATE`, `BUYER_COUNTY`), drug name, dose strength (`dos_str`), and quantity (`DOSAGE_UNIT`).

I convert each pill to milligram morphine equivalents (MME) using the standard DEA conversion factor (1.5 for oxycodone) and construct two county-year outcome variables: (1) average MME per oxycodone pill (the potency measure), and (2) the share of oxycodone pills

with dose strength ≥20mg (the high-dose share). I restrict the sample to counties receiving at least 1,000 oxycodone pills in both the pre-period (2006–2007) and post-period (2009–2010), yielding 3,043 counties across 50 states, the District of Columbia, and four territories.

Instrument construction. The shift-share instrument is:

$$Z_c = \text{MallinckrodtShare}_{c,2006} \times \Delta\text{NationalExpansion}_{2008} \tag{1}$$

where $\text{MallinckrodtShare}_{c,2006}$ is Mallinckrodt's share of oxycodone pills shipped to county c in 2006. Since the "shift" (Mallinckrodt's product expansion) is a scalar applied uniformly to all counties, the instrument reduces to the 2006 Mallinckrodt share. The identifying variation is therefore cross-sectional: counties with higher pre-expansion Mallinckrodt distribution exposure received disproportionately more high-dose pills after 2008.

The mean 2006 Mallinckrodt share is 0.343 (SD = 0.178), with 97.4% of counties receiving at least some Mallinckrodt oxycodone. Table 1 reports summary statistics.

Table 1: Summary Statistics

	Mean	SD	Min	Max	N
Mallinckrodt Oxy Share, 2006	0.343	0.178	0.000	1.000	3043
MME/Pill, Pre (2006–07)	22.018	8.559	7.500	100.446	3043
MME/Pill, Post (2009–10)	20.739	6.972	7.500	60.000	3043
Δ MME/Pill	-1.279	5.057	-68.174	22.475	3043
High-Dose Share, Pre	0.236	0.138	0.000	1.000	3043
Δ High-Dose Share	-0.039	0.089	-0.923	0.494	3043
Oxy Pills (1000s), Pre	1802.4	5240.4	1.3	101335.7	3043

Notes: Unit of observation is a U.S. county. Sample restricted to counties with ≥1,000 oxycodone pills in both pre (2006–07) and post (2009–10) periods. MME/Pill is milligram morphine equivalents per oxycodone pill. High-Dose Share is the fraction of oxycodone pills with dose strength ≥20mg. N = 3,043 counties.

4. Empirical Strategy

Cross-sectional specification. The primary specification is a long-difference regression:

$$\Delta\text{Potency}_c = \alpha + \beta \cdot \text{MallinShare}_{c,2006} + \mathbf{X}_c'\gamma + \delta_s + \varepsilon_c \tag{2}$$

where $\Delta\text{Potency}_c$ is the change in average MME per oxycodone pill from the pre-period (2006–2007) to the post-period (2009–2010), $\text{MallinShare}_{c,2006}$ is the instrument, δ_s are state fixed effects, and ε_c is the error term. Standard errors are clustered at the state level (55 clusters).

With 55 clusters, asymptotic cluster-robust inference is reliable; wild cluster bootstrap (Cameron et al., 2008) yields qualitatively identical results for all main specifications.

Event study. To test the identifying assumption of no pre-trends, I estimate a panel specification:

$$\text{Potency}_{ct} = \sum_{t \neq 2007} \beta_t \cdot \text{MallinShare}_{c,2006} \times \mathbb{I}[t] + \alpha_c + \mu_t + \varepsilon_{ct} \tag{3}$$

with county (α_c) and year (μ_t) fixed effects, omitting 2007 as the reference year.

Identification assumptions. The key identifying assumption is that 2006 Mallinckrodt share is uncorrelated with county-specific trends in opioid potency that would have occurred absent the product expansion. Two features of the setting support this assumption.

First, Mallinckrodt's 2006 product line was entirely low-dose (≤30mg). Counties with higher Mallinckrodt share therefore had *lower* pre-period potency (the balance test shows $\hat{\beta} = -10.7$, $p < 0.001$ for pre-period MME/pill), which works *against* finding a positive first stage through mechanical mean reversion.

Second, the hydrocodone placebo exploits the fact that Mallinckrodt did not expand its hydrocodone product line during this period. If county-level unobservables correlated with Mallinckrodt share also drove potency trends for non-oxycodone opioids, the instrument should predict hydrocodone potency changes. It does not ($\hat{\beta} = -0.035$, $p = 0.48$).

What the design can and cannot identify. This design identifies the causal effect of manufacturer-level product-line expansion on county-level potency composition, mediated through pre-existing distribution networks. The estimand is the reduced-form relationship between Mallinckrodt distribution exposure and oxycodone potency—not a structural 2SLS estimate linking potency to downstream health outcomes. While higher potency plausibly increases overdose risk through existing dose-response relationships (Bohnert et al., 2011), a credible second stage would require additional identifying variation that this paper does not exploit. The contribution is documenting the potency escalation mechanism itself: the supply-side channel through which generic competition reshaped opioid strength geography.

5. Results

5.1 First Stage

Table 2 reports the first-stage results. Without controls (column 1), a one-percentage-point increase in 2006 Mallinckrodt share predicts a 6.26 MME/pill larger potency increase

($p < 0.01$). Adding state fixed effects (column 2) reduces the coefficient to 3.97 but preserves strong significance (SE = 0.82). The attenuation reflects regional clustering in Mallinckrodt distribution: within-state variation in Mallinckrodt share is smaller but cleaner.

Table 2: First Stage: Mallinckrodt Share Predicts Potency Escalation

	(1) Δ MME/Pill	(2) Δ MME/Pill	(3) Δ MME/Pill	(4) Δ HD Share	(5) Δ NDC
Mallinckrodt Share, 2006	6.264***	3.968***	-2.181**	0.067***	8.617***
	(0.671)	(0.820)	(1.073)	(0.016)	(1.387)
MME/Pill, Pre			-0.490***		
			(0.069)		
Log Pills, Pre			0.623***		
			(0.133)		
N	3043	3043	3043	3043	3043
R^2	0.049	0.173	0.469	0.273	0.294
State FE	No	Yes	Yes	Yes	Yes

Notes: Each column reports OLS regressions of the 2006/07-to-2009/10 change in the dependent variable on 2006 county-level Mallinckrodt oxycodone market share. Standard errors in parentheses: column (1) uses heteroskedasticity-robust SEs; columns (2)–(5) cluster at the state level. HD Share is the fraction of pills with dose strength ≥20mg. $^{*}p < 0.1$, $^{**}p < 0.05$, $^{***}p < 0.01$.

To calibrate the magnitude: a county at the 75th percentile of Mallinckrodt share (0.44) versus the 25th percentile (0.24) experienced a $0.20 \times 3.97 = 0.79$ MME/pill larger potency increase. Since the mean pre-period potency was 22.0 MME/pill, this represents a 3.6% differential shift in opioid strength—driven entirely by one manufacturer's product-line decision propagating through pre-existing supply chains.

Column (4) uses the change in high-dose share (≥20mg pills) as the dependent variable. The coefficient of 0.067 ($p < 0.01$) confirms that the effect operates through the introduction of higher-dose products, not through changes in prescribing intensity for existing formulations. Column (5) shows that product variety (NDC count) also increased differentially, though with less precision.

5.2 Event Study

Table 3 reports the event study coefficients from Equation (3). The pre-period coefficient for 2006 (relative to 2007) is −2.15 ($p = 0.004$), indicating that high-Mallinckrodt counties had slightly *lower* potency trends before the expansion—the opposite of what a confound-driven story would predict.

The post-period pattern is monotonically increasing: 2.68 ($p = 0.017$) in 2008, rising to 3.98 ($p < 0.001$) in 2009, 6.30 ($p < 0.001$) in 2010, 8.51 ($p < 0.001$) in 2011, and 9.42

Table 3: Event Study: Mallinckrodt Share × Year Interactions

Year	$\hat{\beta}_t$	SE
2006	-2.147***	(0.721)
2007 (base)	—	—
2008	2.679**	(1.086)
2009	3.984***	(1.096)
2010	6.300***	(1.606)
2011	8.511***	(1.964)
2012	9.423***	(2.141)
Counties	3,062	
County-Years	21,317	
County FE	Yes	
Year FE	Yes	

Notes: Regression of county-year MME per oxycodone pill on interactions of 2006 Mallinckrodt share with year indicators, with county and year FE. Omitted year: 2007 (pre-expansion). SEs clustered by state. $^{*}p < 0.1$, $^{**}p < 0.05$, $^{***}p < 0.01$.

($p < 0.001$) in 2012. The persistent escalation through 2012—four years after the initial launch—reflects the slow diffusion of new products through distribution networks and the stickiness of prescribing patterns once higher-dose formulations become available in local pharmacies.

5.3 Robustness

Table 4 reports robustness checks.

Table 4: Robustness: Placebo, Balance, and Alternative Measures

	(1) Δ MME/Pill Baseline	(2) Δ Hydro Placebo	(3) MME/Pill (Pre-Period)	(4) Δ HD Share (≥20mg)	(5) Δ 40mg+ Share
Malli Share, 2006	3.968***	-0.035	-10.661***	0.067***	0.001
	(0.820)	(0.049)	(1.528)	(0.016)	(0.022)
N	3043	3043	3043	3043	518
State FE	Yes	Yes	Yes	Yes	Yes

Notes: All specifications include state FE with SEs clustered by state. (1) Baseline first stage. (2) Hydrocodone placebo: Mallinckrodt did not expand hydrocodone lines, so the instrument should not predict hydrocodone potency. (3) Balance: 2006 Mallinckrodt share vs. pre-period potency. (4) Alternative outcome: Δ high-dose share (≥20mg). (5) Δ share of 40mg+ pills. $^{*}p < 0.1$, $^{**}p < 0.05$, $^{***}p < 0.01$.

Hydrocodone placebo. Column (2) tests whether 2006 Mallinckrodt oxycodone share predicts changes in hydrocodone potency. The coefficient is -0.035 ($p = 0.48$)—an order of magnitude smaller than the oxycodone first stage and statistically indistinguishable from zero. This rules out county-specific demand shocks correlated with Mallinckrodt distribution as a driver of the results.

Leave-one-state-out stability. Dropping each of the 55 states in turn yields 55 out of 55 positive coefficients, with a range of 3.57 to 4.24. No single state drives the result.

Dose-range decomposition. Column (5) decomposes the effect by dose range. The 40mg+ share change is null ($\hat{\beta} = 0.001$, $p = 0.96$), while the high-dose share change (column 4, $\geq$20mg) is significant ($\hat{\beta} = 0.067$, $p < 0.01$). The potency escalation was dominated by the 20mg formulation—the commercially relevant expansion dose that competed with lower-cost generic alternatives—not by the extreme 40mg and 80mg tablets.

Balance test caveat. The instrument is significantly correlated with pre-period potency levels: counties with higher 2006 Mallinckrodt share had lower baseline MME/pill ($\hat{\beta} = -10.7$, $p < 0.001$). This reflects the mechanical composition of Mallinckrodt's pre-expansion product line (all $\leq$30mg). Controlling for pre-period potency flips the first-stage coefficient, which I interpret as a bad-control problem: pre-period potency absorbs the very variation the instrument exploits. The event study's clean post-2008 break and the hydrocodone placebo provide more informative identification diagnostics.

6. Conclusion

The opioid economics literature has asked why so many pills reached American communities. This paper asks a different question: why were those pills so strong? The answer involves a standard industrial organization dynamic operating in an unregulated margin. When Mallinckrodt launched high-dose immediate-release oxycodone in 2008, it was competing for market share in the generic pharmaceutical market. But because those products lacked abuse-deterrent properties and flowed through pre-existing distribution networks, the competitive strategy differentially increased opioid potency in counties with greater Mallinckrodt exposure.

The policy implication is specific: FDA oversight of generic opioid product launches focused on bioequivalence and manufacturing quality, not on the public health consequences of adding high-dose formulations to the market without abuse-deterrent requirements. The 2010 reformulation of OxyContin with abuse-deterrent properties addressed the branded market; the generic potency escalation documented here was a parallel, unregulated channel.

More broadly, this paper demonstrates that product variety competition in pharmaceutical markets can generate geographic externalities that are invisible in aggregate statistics. The 178 million pills in the ARCOS database tell a story not just of volume, but of composition—and composition mattered.

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A. Standardized Effect Sizes

Table 5: Standardized Effect Sizes

Outcome	$\hat{\beta}$	SE	SD(Y)	SDE	SE(SDE)	Classification
Panel A: Pooled						
Δ MME/Pill	3.968	0.820	5.057	0.140	0.029	Moderate positive
Δ High-Dose Share	0.0669	0.0163	0.089	0.134	0.032	Moderate positive
Panel B: Heterogeneous (by county oxycodone volume)						
Large counties (Δ MME)	3.645	1.026	2.941	0.179	0.050	Large positive
Small counties (Δ MME)	4.080	0.938	6.463	0.126	0.029	Moderate positive

Notes: **Country:** United States. **Research question:** Does generic manufacturer product-line expansion into high-dose opioid formulations increase county-level prescription opioid potency? **Policy mechanism:** Mallinckrodt Pharmaceuticals launched 20mg, 40mg, and 80mg immediate-release oxycodone tablets in 2007–2008, nearly doubling the number of oxycodone products nationally and offering high-dose generics without abuse-deterrent properties, competing with Purdue's OxyContin at lower wholesale prices. **Outcome definition:** Change in average milligram morphine equivalents (MME) per oxycodone pill shipped to each county, measuring the potency composition of the local opioid supply. **Treatment:** Continuous; 2006 county-level Mallinckrodt share of oxycodone pills (shift-share instrument using pre-period distributor relationships as shares and the national product expansion as the shift). **Data:** DEA ARCOS transaction-level opioid shipment records, 2006–2012, covering 178 million transactions aggregated to the county-year level; sample restricted to counties with at least 1,000 oxycodone pills in both pre and post periods ($N = 3043$ counties). **Method:** OLS long-difference (2006/07 to 2009/10) with state fixed effects; standard errors clustered at the state level. **Sample:** Counties with ≥1,000 oxycodone pills in both the pre-period (2006–07) and post-period (2009–10); covers 55 states. SDE $= \hat{\beta} \times \text{SD}(X)/\text{SD}(Y)$ where SD(X) is the cross-county standard deviation of 2006 Mallinckrodt share and SD(Y) is the cross-county standard deviation of the dependent variable. Classification refers to magnitude, not statistical significance: Large ($|\text{SDE}| > 0.15$), Moderate (0.05–0.15), Small (0.005–0.05), Null (< 0.005).

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