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Off-label use of recreational cannabis: Acid reflux in Colorado

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Abstract

Medical cannabis access has been shown to affect clinical health outcomes and health care spending. Unlike medical access, which requires a doctor's recommendation for treatment and only applies to the limited conditions approved under the state's medical cannabis program, recreational access makes cannabis available over-the-counter (OTC). This may create additional benefits through off-label cannabis use to treat unlisted conditions, such as acid reflux, which affects two out of three Americans. Using the roll out of recreational dispensaries in Colorado in 2014, we estimate the change in retailers' market share of antacid medications using a difference-in-differences design. Antacid market share decreases after a dispensary enters a county by 0.85 percentage points. Decreases come from histamine receptor antagonists and proton pump inhibitors. Decreased antacid use may occur through direct substitution for OTC antacids, through changes in dietary behaviors that reduce antacid use, or both. More work is needed to disentangle these two effects.

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1. Introduction

Evidence is accumulating that medical access to cannabis affects clinical practice and health care spending in the United States. Bradford and Bradford (2016, 2017, 2018) find that after states legalized access to medical cannabis dispensaries, use of prescription drugs for which cannabis could serve as a clinical alternative fell. Decreases came from prescription drugs used on- and off-label to treat anxiety disorders, depression and mood disorders, nausea, pain, psychosis, seizure disorders, sleep disorders, and spasticity for Medicaid and Medicare recipients. Patient-level studies document similar decreases in prescription drug use from medical cannabis access (Stith et al., 2018a; Vigil et al., 2017). Bradford and Bradford (2018) estimate Medicare spending would decrease by $1.4-1.7 billion annually if all states allowed medical cannabis access via dispensaries.

As states begin to legalize *recreational* access to cannabis, it begs the question: does recreational access also bring clinical care and health care spending benefits? If recreational access facilitates existing medical use, we would expect additional benefits to be small. However, benefits may be much larger if recreational access eases off-label use to treat conditions not approved under state medical cannabis programs, including less severe conditions or conditions with weaker evidence from medical research.[1] Medical cannabis requires that a clinical provider recommend the drug if a patient presents with an illness listed on the state medical cannabis program (Klofas and Leteney 2012). Recreational dispensaries do not. To get a sense of the potential magnitude of these benefits, consider prescription drugs, where a third of all prescriptions are off-label (Bradford, Turner, and Williams 2018).

We investigate whether recreational access facilitates off-label use of cannabis for a particularly widespread unlisted medical condition. Gastroesophageal reflux disease (GERD), also known as acid reflux or heartburn, affects more than two thirds of Americans (Cohen et al., 2014) and in 2014 Americans spent $2.5 billion dollars on antacids (CHPA 2018). Among 33 state medical cannabis program (plus DC), not one included GERD among their qualifying conditions for medical cannabis use.[2] Using retail scanner data in a difference-in-differences design, we measure how the roll out of recreational dispensaries in Colorado affected sales of over-the-counter (OTC) antacids.

In addition to its broad impact, we focus on GERD for two reasons. First, cannabis may be a clinical alternative to OTC antacids to treat GERD. Though federal barriers in the United States limit medical research (Stith and Vigil 2016), a European study found that, in both dogs and humans, cannabis reduces meal-induced transient lower esophageal sphincter relaxations, the principle mechanism in GERD (Beaumont et al. 2009). Users self-report cannabis effectiveness

[1] Medical access to cannabis has been shown to decrease cannabis prices (Anderson, Hansen and Rees 2013), suggesting that medical cannabis is diverted into recreational markets. Given this, we would expect treatment of unlisted conditions to occur with medical access as well, primarily through two pathways: off-label use by medical cannabis patients to treat unlisted conditions and self-treatment from cannabis purchased in the illegal market. Recreational access would amplify the effects of each pathway.

[2] Many states include nausea among their qualifying conditions, typically as arises from cancer treatment. Milder forms of nausea is a symptom of GERD and nausea is also a potential side effect of proton pump inhibitors used to treat GERD.

to treat symptoms associated with gastrointestinal distress, including nausea, lack of appetite, and gastrointestinal pain (Stith et al, 2018b).

Second, some OTC antacids carry significant risks, particularly for older adults, which could allow for potential welfare gains. The American Geriatrics Society recommends older adults avoid antacids with histamine receptor antagonists (H2) and proton pump inhibitors (PPI) due to concerns that they lower bone mineral density (Bahtiri et al. 2016), increase the risk of hip fractures (Adams et al. 2016), increase the risk of cognitive impairment (Gomm et al. 2016), and increase the severity of *Clostridium difficile* infections (Stewart et al. 2013).[3]

Our work highlights a new set of benefits from access to cannabis distinct to *recreational* cannabis legalization: greater off-label cannabis use for conditions not approved under medical access programs. While broader, social risks associated with recreational legalization are well-documented (Anderson and Rees 2014), benefits to clinical care from off-label use are unrecognized. Yet they may be sizable. We focus on just one potential therapeutic use for recreational cannabis, GERD, and our estimates suggest nationwide recreational access to cannabis would have decreased 2014 OTC antacid market share by about 0.8 percentage points or spending by about $267 million.

2. Methods

2.1. Data

Retail scanner data on antacids and over-the-counter medication come from Nielsen through the Kilts Center for Marketing. Data include all monthly individual product sales for stores in the Nielsen sample.[4] The sample includes all stores in the Nielsen panel dataset between 1/2013 and 12/2015.[5] For our analysis by antacid drug type, we used online manufacturer descriptions to identify active ingredients and group products into three categories: two types of acid blockers, H2 and PPI, and acid neutralizers (calcium-, aluminum-, or magnesium-based formulates).

Recreational dispensary zip code data come from the Colorado Department of Revenue and were matched to counties using the United States Department of Housing and Urban Development's zip code-county crosswalk for the first quarter of 2014. Medical cannabis patient information is from the Colorado Department of Public Health's Medical Cannabis Registry and county-level population data are from U.S. Census Bureau.

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[3] Risks to older adults from cannabis are poorly understood, however, one study found older users employed strategies to reduce cannabis harms (Lau et al. 2015).

[4] Researchers own analyses calculated (or derived) based in part on data from The Nielsen Company (US), LLC and marketing databases provided through the Nielsen Datasets at the Kilts Center for Marketing Data Center at The University of Chicago Booth School of Business.

[5] Note, our panel is not balanced: stores enter and exit the Nielsen panel between 2013 and 2015. The average number of observations per store is 34.7. 136 stores out of 746 stores have fewer then 36 store-months during this time period. In our regressions we included stores with fewer than 36 observations, giving us an unbalanced panel. In robustness checks, we restricted the sample to stores with a balanced panel. Results were very similar to those presented here.

Table I: Summary Statistics

	N	mean	sd	min	max
Panel A: Store (746 Stores)					
Units, antacids	24,860	348.1	301.3	3	2,475
Units, all OTC	24,860	2,519	2,138	23	19,690
Share, antacid	24,860	14.56	4.234	2.622	47.62
Rec Dispensary	24,860	0.545	0.498	0	1
Med Marijuana Share	24,860	2.095	0.668	0.505	5.151
Population	24,860	386,574	243,931	1,353	680,658
Panel B: Store-Drug Type (746 Stores, 2,238 Store-Drug Types)					
Share, acid neutralizer	24,860	68.18	8.770	24.24	100
Share, H2	24,860	15.98	4.324	0	61.67
Share, PPI	24,860	15.84	7.479	0	66.67
Rec Dispensary	74,580	0.518	0.500	0	1
Med Marijuana Share	74,580	2.095	0.668	0.505	5.151
Population	74,580	386,574	243,928	1,353	680,658

2.2. Measures

Our outcome variable is monthly OTC antacid market share. Market share avoids scale effects from store-level differences in aggregate demand. For our store analysis, we divide unit sales of OTC antacids by unit sales of all OTC medications for each store for each month, giving one observation per store-month. Average antacid market share over this period was 14.56%, as seen in Table I. For our category analysis, we divide unit sales of each category of OTC antacids by total unit sales for OTC antacids, giving three observations per store-month.[6] Acid neutralizers' market share is greatest, at 68% of total antacid sales. H2 and PPI market shares are similar, on average, at about 16% each.

Our treatment variable is county-level recreational cannabis access by month. We use the existence of any recreational dispensaries in that county-month. Cannabis became legally available for purchase without a doctor's referral from dispensaries with recreational licenses as early as 1/1/2014. As seen in Figure 1, dispensary access expanded in 2014, varying from 0, including some counties that banned the sale of recreational cannabis, to a maximum of 101 in Denver County.

[6] Some stores have two or one category per time period across the panel because they do not stock all three drug types.

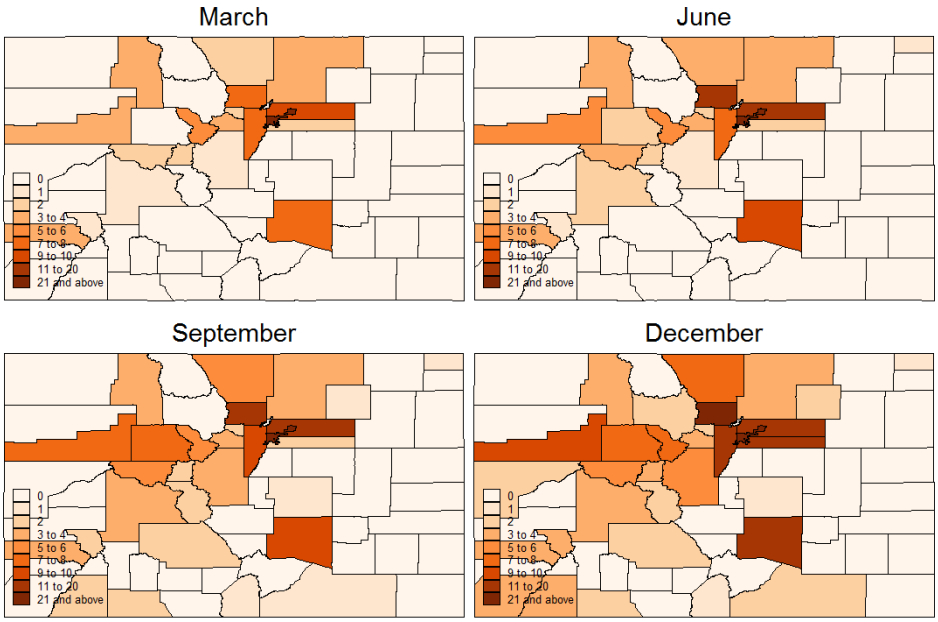

Figure 1: Dispensary Rollout in Colorado in 2014

2.3. Empirical Analysis

For our difference-in-differences estimator, we use the following regression specification:

$$share_{st} = \alpha_s + \beta Rec_{ct} + \gamma MM_{ct} + \delta_{cm} + \delta_{cy} + \varepsilon_{st} \quad (1)$$

where *s* is a store, *c* is a county, and *t* is the month-year. The coefficient β estimates the change in antacid market share with recreational access, where Rec_{ct} denotes dispensary entry in county *c* in month-year *t*. To control for county-level seasonality that occur from different patterns in tourism, we include county-month and county-year fixed effects. We include county-level population, pop_{ct}, to control for changes in the composition of demand related to migration. We include the share of 2010 population enrolled in the medical marijuana program, MM_{ct}, to control for changes in access to medical cannabis. Standard errors are clustered by county.

For our category analysis, we interact recreational access to cannabis with indicator variables for H2s and PPIs. Fixed effects are at the store-category level. Observations are for a store *s*, for drug type *d*, in month-year *t*.

$$share_{sdt} = \alpha_{sd} + \beta_1 Rec_{ct} + \beta_2[Rec_{ct} * H2_d] + \beta_3[Rec_{ct} * PPI_d] + \gamma MM_{ct} + \delta_{cm} + \delta_{cy} + \varepsilon_{sdt} \quad (2)$$

In both the store and store-category, we vary the window of the period of the analysis to ensure our results are robust. We begin with the widest window, from 2013-2015, and narrow to seven months before and after cannabis became recreationally legal, 5/2013-7/2014. In this last sensitivity check with a restricted panel, we no longer have sufficient variation as to include county-month fixed effects. In this specification, we include month and year fixed effects instead.

We weight observations by the county's population in 2014 using weighted least squares (WLS). Weighting is justified if sampling is endogenous or the degree of intracluster correlation is low and the variance in the number of observations per cluster is high (Solon, Haider and Wooldridge 2015). In our case, sampling may be endogenous because chain stores are overrepresented in the Nielsen data and independent stores may be more likely in less populous counties. We also observe large variation in the number of observations per cluster. In these cases, WLS will increase efficiency.[7]

In addition to our main specification, we estimate an event study specification to look for pretrends and observe the temporal pattern of antacid sales after recreation access. The specification we use is

$$share_{st} = \alpha_s + \sum_{k=-6}^{6} \gamma_k \{K_{st} = k\} + \gamma_{K-} 1\{K_{st} \leq -7\} + \gamma_{K+} 1\{K_{st} \geq 7\} + \gamma MM_{ct} + \delta_{cm} + \delta_{cy} + \varepsilon_{st} \quad (3)$$

The omitted category is the month before recreational dispensary entry. We plot the coefficients γ_k, γ_{K-} and γ_{K+} in Figure 2.

Table II: Antacids Market Share & Recreational Cannabis Access

	(1) 2013-2015	(2) 2013-2014	(3) 5/2013-7/2014
Rec Dispensary	-0.431***	-0.842***	-0.150**
	(0.051)	(0.060)	(0.057)
Med Marijuana Share	0.636**	1.348***	0.791**
	(0.259)	(0.461)	(0.343)
Population	-0.491	-0.858	-0.655
	(0.704)	(0.966)	(0.801)
Constant	19.149**	22.327*	20.630*
	(9.076)	(12.443)	(10.446)
Fixed Effects	Store, CountyXMonth, CountyXYear		Store, County, Year
Estimation Framework	WLS	WLS	WLS
Observations	24,846	16,596	10,399
R-squared	0.861	0.865	0.868

Notes: Coefficients are measured in percentage points (0 to 100.) Clustered standard errors are in parentheses. p<0.01 ***, p<0.05 **, p<0.1 *

3. Results

Our regression results in Table II suggest that cannabis acts as a substitute for OTC antacids.[8] Access to a dispensary initially decreased OTC antacid market share by 0.15

[7] In robustness checks, we estimated Tables II and III using OLS. WLS and OLS have different probability limits, making the comparison of the two a useful diagnostic for model misspecification (DuMouchel and Duncan 1983). In our case, we see that the WLS estimates tend to be more precise, but the estimates are not very different, suggesting that heteroscedasticity across counties is likely present.

[8] The conclusions drawn from the Nielsen data are those of the researchers and do not reflect the views of Nielsen. Nielsen is not responsible for, had no role in, and was not involved in analyzing and preparing the results reported herein.

percentage points. Over the course of the year after recreational access, recreational dispensary entry decreased antacid market share by 0.8 percentage points or 5.5%. If individuals travel across county lines to obtain cannabis, we underestimate the effect. The effect seems strongest between six and twelve months after recreational access (column 2). If we extend the window out to two years after legalization in Colorado, the magnitude of the effect decreases by about half.

Figure 2 plots coefficients from our event-study specification. We find no evidence that our results are driven by a pre-trend. Instead, we see a dramatic decrease in the month of dispensary entry. Sales decrease sharply for the first three months, leveling out around a decrease of 0.5 percentage points, which is close to the estimate in column 1 of Table II. This pattern is also reflected in columns of Table II, where the decrease in market share is smaller when estimated using the shorter panel, which weights the coefficient toward the effect in the first few months post-entry.

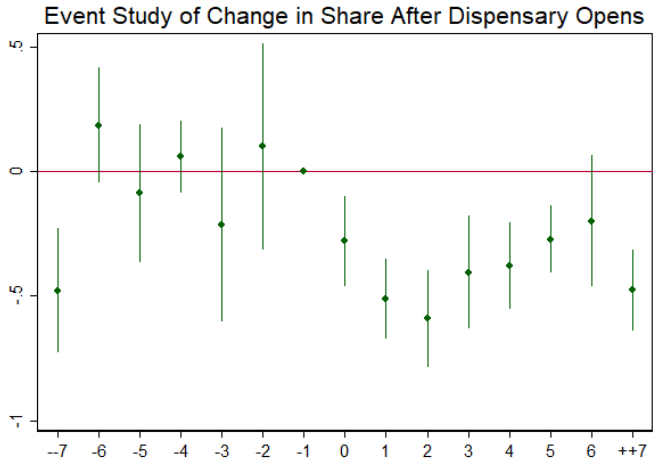

Figure 2: Event Study of OTC Antacids Share Before and After First Dispensary

Counties with later dispensary entry, which help identify the effect in column one of Table II, seem to have a weaker substitution response; the coefficients are smaller than when we use the 2013-2014 sample. This may be because of spillovers, e.g. residents travel to nearby counties to get access to cannabis without a prescription. Alternatively, conditional on the absence of a county-wide ban, dispensaries may first enter markets with greater latent cannabis demand.

Table III indicates that decreased demand for H-2s and PPIs rather than acid neutralizers drives the decrease in antacid market share. Dispensary entry decreases market share in 2014 by 1.3 percentage points for H2 and 2.2 percentage points for PPIs. These changes are in the range of 6-15%. Recall that these classes of antacids are stronger and more effective than acid neutralizers, the omitted category, yet they also have more contraindications for older people.

Table III: Antacids Market Share by Drug Type & Recreational Cannabis Access

	(1) 2013-2015	(2) 2013-2014	(3) 5/2013-7/2014
Rec Dispensary	1.093***	1.063***	0.656***
	(0.201)	(0.206)	(0.160)
Dispensary X H2	-1.262***	-1.334***	-0.898***
	(0.354)	(0.323)	(0.236)
Dispensary X PPI	-2.192***	-2.132***	-1.108***
	(0.274)	(0.273)	(0.261)
Med Marijuana Share	0.038*	0.016	-0.037
	(0.022)	(0.027)	(0.032)
Population	0.053	0.082**	0.011
	(0.054)	(0.036)	(0.046)
Constant	33.223***	32.864***	33.891***
	(0.675)	(0.483)	(0.578)
Fixed Effects	Store, CountyXMonth, CountyXYear		Store, County, Year
Estimation Framework	WLS	WLS	WLS
Observations	74,568	49,845	31,197
R-squared	0.981	0.981	0.983

Notes: Coefficients are measured in percentage points (0 to 100.) Clustered standard errors are in parentheses. p<0.01 ***, p<0.05 **, p<0.1 *

4. Discussion: Clinical link between Cannabis and GERD

To our knowledge, we are the first to show that recreational access to cannabis may substitute for the use of drugs that inhibit gastric acid secretion. We propose two mechanisms that could explain the link between cannabis and GERD symptom management. First, cannabis may directly substitute for PPI and H-2s by reducing tightening of the lower esophageal sphincter (Beaumont et al. 2009), mediating GI homeostasis (Abdel-Salam et al. 2015) or enhancing resolution of gastrointestinal (GI) tract inflammation (Wallace et al. 2013). Cannabis inhibits stimulated gastric acid secretion and increases the secretion of gastric mucus, an important mucosal protective mechanism (Abdel-Salam et al., 2015).[9] By decreasing gastric acid secretion, subjects with GERD may experience fewer symptoms. This would be consistent with historical cannabis use for GI distress (Russo 2007), individual self-reports of such use (Stith et al., 2018), and the approval of cannabis to treat severe nausea by state medical cannabis programs. Since five out of six cannabis users consume for health as well as recreational purposes (Pacula et al. 2016), a decrease in antacid use may occur in response to intentional treatment of GERD symptoms or as a by-product from recreational or other medical use.

Alternatively, cannabis use may indirectly decrease antacid use by modifying dietary behaviors. The endocannabinoid system plays a major role in the brain-gut axis, regulating energy balance through appetite control. Phytocannabinoid consumption excites the motivation to eat, visceral satiety, and cravings for different types of macronutrients (Kirkham 2009), i.e., it is possible that

[9] For example, in a study on human subjects, Nalin et al. (1978) found that smoking cannabis for more than 2 days a week was associated with low gastric acid output.

cannabis use may change the composition of food, drink, and medication consumed in ways that may relieve GERD symptoms or GI distress. Further supporting this conjecture, other studies have found that medical cannabis access reduces consumption of alcohol (Anderson et al. 2013; Baggio et al. 2017), a substance with a pro-oxidant effect on the gut-barrier (Hsu et al. 2015). Modification of dietary behaviors would be consistent with lower body mass after medical access (Sabia et al. 2015), potentially due to down-regulation of CB_1R, a cannabinoid receptor in the brain associated with gastrointestinal activity (Di Marzo et al. 2001).

5. Conclusion

Using a natural experiment in Colorado, we demonstrate an overlooked, potential benefit from recreational access to cannabis: off-label cannabis use. We focus on GERD, a common condition unlisted among state medical cannabis programs, but theoretically influenced by cannabis use. Dispensary entry decreased retailers' antacid market share. We find no evidence that a pre-trend drives our results. Decreases in acid-blocking medications risky for older adults drove the decline. The clinical link between cannabis and GERD may occur through direct substitution of cannabis for OTC antacids, through changes in dietary behaviors that preclude antacid use, or both. More work is needed to disentangle these two effects as well as to identify appropriate dosing and assess the likelihood of users developing a tolerance to cannabis' effects. More work is also needed to quantify the risk-benefit tradeoffs between cannabis and conventional OTC antacids, particularly among older adults for whom some conventional antacids can increase morbidity. Spending on OTC antacids in 2014 would have decreased by $267 million given nationwide recreational access. Future work should assess clinical care benefits from recreational access for other unlisted conditions to better inform cannabis access policies.

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