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Assessing the impact of drug courts on provider-directed marketing efforts by manufactures of medications for the treatment of opioid use disorder

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A B S T R A C T

Background: Opioid use disorder (OUD) has become an increasingly consequential public health concern, especially in the United States where 47,600 opioid overdose deaths occurred in 2017 (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019). Medications for OUD (MOUD) are effective for decreasing opioid-related morbidity and mortality, including within the criminal justice system (Hedrich et al., 2012; Medications for Opioid Use Disorder Save Lives, 2019; Moore et al., 2019).While a stronger evidence base exists for agonist MOUD than for antagonist MOUD, a national study of drug courts found that half prohibited agonist MOUD (Matusow et al., 2013).Furthermore, recent media reports suggest that the pharmaceutical manufacturer of an antagonist MOUD has marketed its product towards drug court judges (Goodnough & Zernike, 2017; Harper, 2017). However, no study to date has systematically examined the relationship between MOUD marketing practices and drug courts. This ecological study examines the association at the county level between MOUD manufacturer payments to prescribers and drug court locations.

Method: We extracted provider-directed payments from Centers for Medicare and Medicaid Services (CMS)'s Sunshine Act Open Payments data 2014–2017, isolating those records mentioning any MOUD. We compared provider-directed payments for two major MOUDs: buprenorphine and extended-release naltrexone, in counties with and without drug courts.

Results: The presence of any adult drug courts in the county is associated with a 7.86 percentage-point increase in the likelihood of providers in that county receiving any MOUD-related payments (about 22.46% of the sample mean, $p < 0.001$) and with a 10.70% increase in the amount of these payments per 1000 county residents ($p < 0.001$). The association between other forms of drug courts such as juvenile drug courts and Driving-Under-the-Influence courts (DUI) courts are less significant and slightly smaller in magnitude compared to those of adult drug courts. We did not find significant difference between payments by the manufacturer of Vivitrol and manufacturers of Zubsolv, Bunavail, and Suboxone (oral forms of buprenorphine).

Conclusions: Our results show an ecological association at the county level between MOUD manufacturer payments to prescribers and drug court presence. However, we did not examine a causal association between these variables.

1. Introduction

Approximately 2.1 million adults in the U.S. have an opioid use disorder (OUD) (Results from the 2016 National Survey on Drug Use and Health: Detailed Tables, 2017). Between 2000 and 2015, rates of opioid-related overdose deaths quadrupled(Dowell, Haegerich, & Chou, 2016), prompting public officials to declare an opioid crisis and President Trump to declare a public health emergency (Gostin, Hodge, & Noe, 2017) and to implement government initiatives to decrease opioid overdose rates (Scholl, Seth, Kariisa, Wilson, & Baldwin, 2019). Individuals with OUD are overrepresented in the criminal justice system (Di Paola et al., 2014). However, incarceration appears largely ineffective for managing OUD, with opioid overdose being the leading cause of death following release from incarceration(Binswanger et al., 2007; Binswanger, Blatchford, Mueller, & Stern, 2013). In response to the opioid overdose crisis, policymakers have called for expanding the utilization of drug courts as an alternative to incarceration for non-violent, drug-related crimes (Christie et al., 2017).

Drug courts have played an important role in the United States since their debut in 1989 (Sharma et al., 2016). Drug courts use programming designed to reduce recidivism and relapse to drug use, including health assessments, judicial monitoring, mandatory treatment, incentive, and graduated sanctions (Drug Courts, 2018). According to the 2014 Painting the Current Picture Survey of the National Drug Court Institute, there were 3057 drug courts in the U.S. as of December 2014, including 1133 adult drug courts, 407 hybrid drug/Driving-Under-the-Influence courts (DUI) court, 262 DUI courts, 305 family courts, and 420 juvenile drug courts (Marlowe, Hardin, & Fox, 2016). The National Drug Court Resource Center (NDCRC) reported 4168 drug treatment court programs as of June 2018. Adult drug courts target adults with

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substance use disorder, while family drug courts target adults with substance use disorder who have children involved in neglect or abuse cases (Development Services Group, 2016). Juvenile drug courts work with youth alcohol and drug offenders; and DUI courts use substance use disorder interventions for those who have pled guilty of driving while under the influence of alcohol or drugs (Harron & Kavanaugh, 2015).Despite their effectiveness at preventing relapse and overdose (Nielsen et al., 2016; Medications for Opioid Use Disorder Save Lives, 2019; Moore et al., 2019), including within the criminal justice system (Hedrich et al., 2012; Moore et al., 2019), access to medications for treating OUD has been restricted in criminal justice settings, including in diversionary programs, such as drug courts, with administrators often preferring non-medication treatment methods (e.g. counseling, support groups) (Friedman & Wagner-Goldstein, n.d.; Krawczyk, Picher, Feder, Student, & Saloner, 2017).

The largest national study of medication availability in adult drug courts found that approximately half restrict the use of methadone and buprenorphine (Matusow et al., 2013), the two forms of medications to treat OUD (MOUD) with the strongest evidence base to date (Nielsen et al., 2016).Both methadone and buprenorphine (agonist treatments) activate the opioid receptors in the brain, potentially causing euphoria if misused, which has led many criminal justice administrators to express concerns about misuse and diversion of the medications (Friedman & Wagner-Goldstein, n.d.; Friedmann et al., 2012; Matusow et al., 2013). Furthermore, Matusow et al. found widespread negative attitudes towards the efficacy of agonist treatments, with a tenth of drug court staff survey respondents viewing methadone as a reward for criminal behavior (Matusow et al., 2013).Additional concerns include cost barriers, limited court staff resources for monitoring medication adherence, and limited access to local medication providers (Matusow et al., 2013). A smaller qualitative study of drug courts and veterans' courts found that judges often view providers of agonist medications with skepticism, suggesting that trust in a local provider may be a prerequisite to allowing agonist medications for drug court participants (Andraka-Christou, 2017).

In the last decade, extended-release naltrexone (an antagonist) has been increasingly utilized in OUD treatment (Alderks, 2017), both inside and outside of the criminal justice system. The medication is a substitute for methadone or buprenorphine; since none of these three medications should be taken simultaneously. Extended-release naltrexone, an antagonist, blocks rather than activates opioid receptors, eliminating misuse liability. Therefore, criminal justice administrators' are less likely to be concerned about misuse or diversion of extended-release naltrexone relative to buprenorphine or methadone (Murphy et al., 2017). Additionally, unlike the common formulations of methadone and buprenorphine that are administered or taken daily, extended-release naltrexone is administered by a physician once per month, with one dose lasting for 28 days. As a result, criminal justice administrators may have fewer concerns about monitoring or supervising extended-release naltrexone, relative to methadone and buprenorphine. Additionally, fewer regulatory restrictions exist for prescribing extended-release naltrexone, including in the criminal justice setting. However, as a more recent medication, extended-release naltrexone has a smaller evidence base than methadone or buprenorphine-naloxone (Jackson, Mandell, Johnson, Chatterjee, & Vanness, 2015). Few studies have directly compared the efficacy of extended-release naltrexone to other forms of MOUD (Lee et al., 2018; Tanum et al., 2017); but existing studies suggest similar efficacy to daily buprenorphine-naloxone for patients (Lee et al., 2018; Tanum et al., 2017), but a higher drop-out rate, which may lead to relapse (Lee et al., 2018; Morgan, Schackman, Leff, Linas, & Walley, 2018). Additionally, a recent study found that during medication utilization, buprenorphine was more protective against opioid overdose than extended-release naltrexone (Morgan, Schackman, Weinstein, Walley, & Linas, 2019). Finally, extended-release naltrexone is less cost-effective than agonist medications (Murphy et al., 2019, 2017) in the criminal justice system.

Recent media reports have suggested that the manufacturer of extended-release naltrexone, Alkermes, has been targeting marketing towards criminal justice administrators, especially drug court judges, likely for the reasons described above (Goodnough & Zernike, 2017; Harper, 2017).Marketing that targets drug courts raises potential ethical issues, because drug court staff have coercive power over participants (e.g. staff can decide whether a participant may use a certain medication), and drug court staff rarely include physicians, leaving decision-making power in the hands of non-medically trained personnel (Andraka-Christou, 2017; Matusow et al., 2013). Furthermore, marketing of extended-release naltrexone to criminal justice administrators may lead them to encourage utilization of a medication with lower cost-effectiveness and a smaller evidence base than agonist medication (Nguyen, Bradford, & Simon, 2019)in a program supported by taxpayer funds.

In response to media reports, in 2017 Senator Kamala Harris called for an investigation into Alkermes' marketing practices(Senator Harris Launches Investigation into Pharmaceutical Manufacturer Alkermes Regarding Opioid Addiction Treatment Manipulation, 2017). Nevertheless, to our knowledge no systematic study has examined MOUD manufacturers' marketing activities towards criminal justice populations or in counties with drug courts. Furthermore, even though media reports focused on Alkermes' activities, no systematic study has compared differences in promotional practices between different types of MOUD manufacturers in counties with drug courts. For example, it is unknown whether marketing practices in counties with drug courts differ based on the medication's agonist or antagonist profile or patent age.

The purpose of our study was to examine and compare marketing practices of manufacturers of buprenorphine (including the formulation buprenorphine-naloxone) and extended-release naltrexone, specifically by examining payments made to physicians in counties with drug courts. We examine payments made to physicians rather than directly to drug courts for the following two reasons. First, while drug court administrators may allow or restrict MOUD in court-mandated treatment programs, drug courts almost never have a prescriber on staff (Andraka-Christou, 2017; Drug Courts, 2018); therefore, any drug court participants accessing MOUD acquire them from a prescriber in an office-based practice or an Opioid Treatment Program outside of the court. Second, to our knowledge there is no publicly available database of payments made from pharmaceutical companies to drug court staff; the Sunshine Act only requires pharmaceutical companies to report payments made to physicians and teaching hospitals (Medicare, Medicaid, Children's Health Insurance Programs: Transparency Reports and Reporting of Physician Ownership or Investment Interests, 42 CFR 402-403, 2013). We excluded methadone from our study, because it can only be prescribed and dispensed for OUD in highly regulated Opioid Treatment Programs, with some states having only a handful of such programs (OTP Directory, 2018). We do not examine payments related to oral naltrexone, given its low efficacy for OUD (Nielsen et al., 2016).

While pharmaceutical companies' marketing practices may involve a range of activities, including direct-to consumer-marketing and promotion aimed at healthcare practitioners, we focus on the latter, which accounts for the greatest share of promotional spending (Schwartz & Woloshin, 2019). Furthermore, a sample of direct-to-consumer spending at the county level was unavailable. Marketing to healthcare professionals includes distribution of free samples, advertisements in medical journals and conferences, and promotional payments in the form of gifts, free meals, travel, and lodging (Schwartz & Woloshin, 2019). Even small gifts appear to promote increased prescribing (Ornstein, Tigas, & Jones, 2016; Steinbrook, 2017) and data about these gifts is publicly available.

Our study may shed light on whether the manufacturer of extended-release naltrexone (as the media reports suggest) has more promotional activities towards prescribers in geographic areas with drug courts as opposed to those without drug courts. We hypothesized a higher rate of

promotional activities for extended-release naltrexone in areas with drug courts as compared to areas without drug courts, because drug court participants may represent a higher share of prescribers' patients in these areas; and manufacturers may know that drug court policies frequently forbid buprenorphine access (Matusow et al., 2013).

Additionally, we hypothesized that counties with adult drug courts would have more promotional activities towards prescribers relative to counties with other types of drug courts (e.g. family drug courts, juvenile drug courts, driving-under-the-influence courts). MOUD has been FDA-approved for adults only, despite research showing its effectiveness in adolescents (Hadland et al., 2017; Hadland et al., 2018; Subramaniam, Levy, & Sullivan, 2013; Trial et al., 2008); therefore, drug court staff may find it more difficult to refer youth in juvenile drug courts to local physicians for MOUD, who may be hesitant to prescribe MOUD to youth (Saloner, Feder, & Krawczyk, 2017).Though almost no research has examined MOUD access in family drug courts, criminal justice administrators may restrict MOUD in those courts due to concern of accidental ingestion by children. Also, among MOUDs, only naltrexone is FDA-approved for alcohol use disorder, the primary problem at issue in driving-under-the-influence courts; therefore, the demand for MOUD may be lower in counties with driving-under-the-influence courts relative to counties with adult drug courts.

We hope to bring attention to the potentially complex relationship between pharmaceutical companies, prescribers, and criminal justice administrators without prescribing capability. Elucidation of this relationship is particularly important given that approximately half of all referrals for public Substance Use Disorder (SUD) treatment programs come from the criminal justice system, including adult drug courts (Taxman, Perdoni, & Harrison, 2007). Nevertheless, given its ecological nature, our study cannot determine whether promotional activities target drug court staff directly (e.g. through educational seminars offered by pharmaceutical companies to judges).

2. Material and methods

2.1. Data

2.1.1. Outcome variable

The first set of dependent variables include a binary indicator for whether physicians in a county received any MOUD-related payments (collectively) in a year and then separately for each MOUD: Bunavail, Suboxone, Zubsolv, Buprenorphine-naloxone, and Vivitrol. Probuphine was only found in Open Payments data 2016–2017, therefore, we did not conduct the analysis separately for Probuphine. The second set of dependent variables consists of the dollar amount of MOUD-related payments (collectively) and the dollar amounts of payments for each specific drug by year.

Our primary data source is the Sunshine Act's Open Payments data 2014–2017 published by the Centers for Medicare and Medicaid Services (CMS). The Open Payments data contains records of all direct payments from pharmaceutical companies to physicians. Each record contains the physician name and address, date of payment, lists up to 5 drugs (or medical devices) that the manufacturer was seeking to promote with the payment, and records a broad classification of the form of payment. We extracted all records that mentioned at least one MOUD and aggregated these payments to the ZIP code level. Since 2014 was the first full year of Open Payments data, we selected that as the starting year for our analysis. In line with prior studies, this study was limited to non-research, non-equity, drug-related payments to physicians, referred herein as promotional payments (Hadland, Krieger, & Marshall, 2017; Nguyen et al., 2019; Perlis & Perlis, 2016). We mapped the ZIP-level data to their corresponding Federal Information Processing Standards (FIPS) codes using the ZIP-county crosswalk file in the R package noncensus (Boland, Parhi, Gentine, & Tatonetti, 2017; Ramey, 2016) which also accounts for cross-county ZIP codes.

We compiled a list of all prescription drugs which incorporate buprenorphine and naltrexone that are used to treat OUD based on prior literature (Clemans-Cope, Epstein, & Kenney, 2019). We included drugs containing buprenorphine hydrochloride or both buprenorphine hydrochloride and naloxone hydrochloride (Bunavail, FDA-approved 2002; Suboxone, FDA-approved 2002; Probuphine, FDA-approved 2016; Zubsolv, 2014; and generic forms of buprenorphine-naloxone) and extended-release naltrexone (Vivitrol, FDA-approved 2010) (Drugs@FDA: FDA Approved Drug Products, n.d.). Sublocade and Cassipa, the very recent FDA approved buprenorphine class drugs, as well as Subutex (the buprenorphine mono product), were not found in Open Payments and Prescriber PUF data and were thus omitted. Additionally, other buprenorphine class drugs (Buprenex, Butrans, and Belbuca), and all methadone products prescribed by physicians were excluded from the analysis because they may also be used for pain management. We excluded other naltrexone class drugs (Revia and all generic forms of naltrexone hydrochloride) because these drugs may be prescribed for alcohol use disorder rather than for OUD.

2.1.2. Key predictors

Our predictors include having any drug court in a county each year, having any adult drug court, and having any other drug court. The other drug courts include DUI courts, hybrid DUI/drug courts, juvenile drug courts, family drug courts, reentry drug courts, campus drug courts, tribal healing to wellness drug courts, co-occurring disorder courts, and veterans treatment courts. We do not consider the incremental effects associated with having one more drug court in a county because $< 5\%$ of counties have > 1 adult drug court.

Implementation year, court type, and location (ZIP codes) of drug treatment court programs were obtained from the 2017 public-use dataset of the NDCRC. The NDCRC has built this dataset from information collected in the NDCRC Annual Drug Court Surveys and a database of grant recipients from the Bureau of Justice Assistance. The data used in this paper was the 2017 version instead of the latest version of the NDCRC drug court database (as of June 2018) because the 2017 version provides more complete data in implementation years of drug court programs. Particularly, 1698 drug courts out of 4168 courts in the 2018 version have missing implementation years while only 886 drug courts of 3431 courts in the 2017 have incomplete data on the implementation. The NDCRC list online is incomplete, because twelve states (IL, HI, MD, MN, NV, NJ, NM, OR, UT, VT, VA, and WY) did not give permission for their data to be public, so we excluded those states in our analyses. We also dropped 110 adult drug courts and 418 other drug courts (including DUI courts, hybrid DUI/drug courts, juvenile drug courts, family drug courts, reentry drug courts, campus drug courts, tribal healing to wellness drug courts, co-occurring disorder courts, and veterans treatment courts) in our baseline analysis because of missing implementation year data. According to the NDCRC, these “missing year” courts are still open; however, the statewide coordinator does not know the year they opened. In order to address this limitation of the NDCRC dataset, we implemented additional analyses based on two assumptions. First, we assumed these 528 drug courts were established before 2014, the first year of our study period. Alternatively, we assumed these drug courts were established in 2017, the last year of our data. We then compared these two additional analyses to the baseline analysis.

2.1.3. Covariates

Adjustments were made for local sociodemographic characteristics, opioid overdose mortality, opioid prescription rates, and access to SUD treatment when studying the associations between drug court programs and MOUD detailing. All county information was lagged by one year. Local sociodemographic characteristics included the following: median household income; percent of rural population; percent of adults aged 19 to 64 with insurance; number of primary physicians per 100 k residents; percent of county that was non-Hispanic African-American; percent of county that was Hispanic; percent of county that was Asian,

Pacific Islander, or American Indian; and the number of opioid-related deaths per 100 k residents. We also controlled for the number of retail opioid prescriptions dispensed per 100 residents, the number of patient-waivered physicians for buprenorphine per 100 k residents, and the concentration of substance abuse treatment facilities.

The county-level demographic and socioeconomic characteristics were obtained from the Robert Wood Johnson Foundation County Health Rankings file. In addition, the percent of adults aged 19 to 64 with insurance for counties is from the U.S. Census Bureau's Small Area Health Insurance Estimates program. The number of retail opioid prescriptions dispensed per 100 residents for counties comes from the Centers for Disease Control and Prevention. We estimated the number of opioid-related deaths per 100 k residents for counties from the National Vital Statistics System of the Centers for Disease Control and Prevention Multiple Cause of Death (MCOD) files for 2013–2016 years. The number of patient-waivered physicians for buprenorphine for states was obtained from the 2017 Active Controlled Substances Act Registrants. We estimated the number of substance abuse treatment facilities for counties from the directories associated with the National Survey of Substance Abuse Treatment Services files in 2014–2016.

2.2. Statistical analysis

We estimated the effects of drug court programs on receipt of MOUD detailing (collectively) and detailing of each MOUD (individually) using logit regressions. The ordinary least squares (OLS) regressions were employed to estimate the effects of drug court programs on the amount of MOUD detailing. The distribution of MOUD-related payments was highly skewed at the county level with 34% zero-value observations and large positive values; therefore, we used the inverse hyperbolic sine transformation of total payments rather than the more traditional log transformation. The inverse hyperbolic sine transformation allows us to define these zeros and can generally be treated like a natural logarithm with large positive values (Burbidge, Magee, & Robb, 1988).

In each regression, county-level sociodemographic characteristics, opioid overdose mortality, opioid prescription rates, and access to SUD treatment were included. In the OLS regressions of MOUD-related payments, we also adjusted for the county populations. State fixed effects and year fixed effects were included with each regression in order to control for unobserved temporal and geographic factors. We do not use county fixed effects because 89.7% of drug courts in the dataset were implemented before our study period. These regressions were implemented in Stata (version 15.1).

3. Results

3.1. Baseline estimations

As of April 2017, in our data set there were 2628 drug courts operating in 39 states (Fig. 1), including 990 adult drug courts and 1638 other drug courts (including DUI courts, hybrid DUI/drug courts, juvenile drug courts, family drug courts, reentry drug courts, campus drug courts, tribal healing to wellness drug courts, co-occurring disorder courts, and veterans treatment courts). We excluded mental health courts and non-specific court programs from the NDCRC database.

Of the 2465 counties in the study, 34% received any MOUD-related payments, according to the Open Payments database; 63.9% of counties in the study received opioid-related payments. To convey to what degree counties experience receipt of any drug related promotional payments, we note that 69.9% of the counties in the study received antibiotics-related payments. These statistics all relate to the time period 2014 to 2016. In that same time period, extended-release naltrexone's manufacturer conducted provider-directed marketing activities in 19.9% of all counties, which is only slightly more than the fraction of counties in which buprenorphine brand manufacturers conducted marketing (17.6% for Suboxone, 16% for Bunavail, and 17.7% for Zubsolv). The distribution of MOUD-related payments was highly skewed at the county level. For example, the top counties targeted for MOUD-related payments in 2014–2017 include Los Angeles and San Diego (CA), Davidson county (TN), Montgomery county (PA), and St. Louis county (MO) which received more than $100,000 each in direct-to-physician payments per year. On average, MOUD manufacturers sent $873.13 as pharmaceutical payments to a typical county annually, which is relatively small compared to marketing payments of non-MOUD opioids ($5752 per county). Vivitrol makers spent $240 on detailing in a typical county, which was larger than spending by other MOUD brand manufacturers ($214 for Suboxone, $196 for Bunavail, and $143 for Zubsolv). Physicians in a typical county reported receiving $2.2 for generic buprenorphine/naloxone drugs.

Table 1 reports the associations between drug courts and MOUD-related provider-directed advertising at the county level. Model 1 compares the likelihood of receiving MOUD-related payments for counties possessing any drug courts versus counties without any drug courts. The results suggest that counties with the presence of any drug courts (vs. counties without any drug courts) had a 61.6% increased odds of receiving any MOUD-related payments ($p < 0.001$). Model 2 compares the amount of MOUD-related payments received between counties with drug courts and counties without such courts. Results of Model 2 show that counties with any drug courts received 63% higher total amount of payments than other locations ($p < 0.001$).

These estimations also indicate that MOUD-specific promotions were concentrated to higher-income geographic areas, urban counties, and counties with higher concentration of white Americans. Noticeably, one additional buprenorphine waiver per 100,000 residents in a county is associated with a 7.5% increased odds of receiving such payments and with a 6.4% increase in the amount of payments (both $p < 0.001$). While opioid overdose mortality is positively associated with the receipt of these payments ($p < 0.001$), we observed a negative relationship between the concentration of substance abuse treatment facilities and MOUD detailing payments ($p < 0.01$).

Results in Table 2 compare receipts of MOUD-related payments for counties possessing adult drug courts (or other drug courts) versus counties without any drug courts. In particular, counties with any adult drug courts (versus counties without any drug courts) had a 69% increased odds of receiving such payments ($p < 0.001$). The presence of adult drug courts is associated with 73.7% higher amount of payments ($p < 0.001$). Counties with other drug courts had a 52.7% increased odds of receiving MOUD detailing ($p < 0.001$) and received 50.5% higher payments compared to counties without any drug court ($p < 0.001$). The effect of adult drug courts is not statistically larger than those of other drug courts. The variance inflation factor (VIF) of the presence of adult drug courts and the presence other drug courts are 1.57 and 1.51 respectively, which indicate that these comparisons do not have multicollinearity issues.

Fig. 2 summarizes the relationship between the presence of drug courts in counties and provider-directed advertising for all MOUDs (collectively) and each specific MOUD (individually). This figure presents the adjusted relative change and its 95% confidence interval in the physician-directed payments attributable to the presence of any drug courts. We found positive associations between the presence of adult drug courts and likelihood of receiving payments for Vivitrol, Suboxone, Zubsolv, and Bunavail, but not for generic buprenorphine-naloxone (Fig. 2a). Particularly, the presence of any drug court in a county significantly increases the odds of receiving payments for Vivitrol by 59% ($p < 0.001$), for Suboxone by 41% ($p < 0.001$), for Zubsolv by 48% ($p < 0.001$), and for Bunavail by 38% ($p < 0.001$). The magnitude of these associations for Vivitrol, Suboxone, Zubsolv, and Bunavail are not significantly different from each other. Fig. 2b shows similar positive associations between the presence of any drug courts and the amount of MOUD-related payments in a county. Similar to the

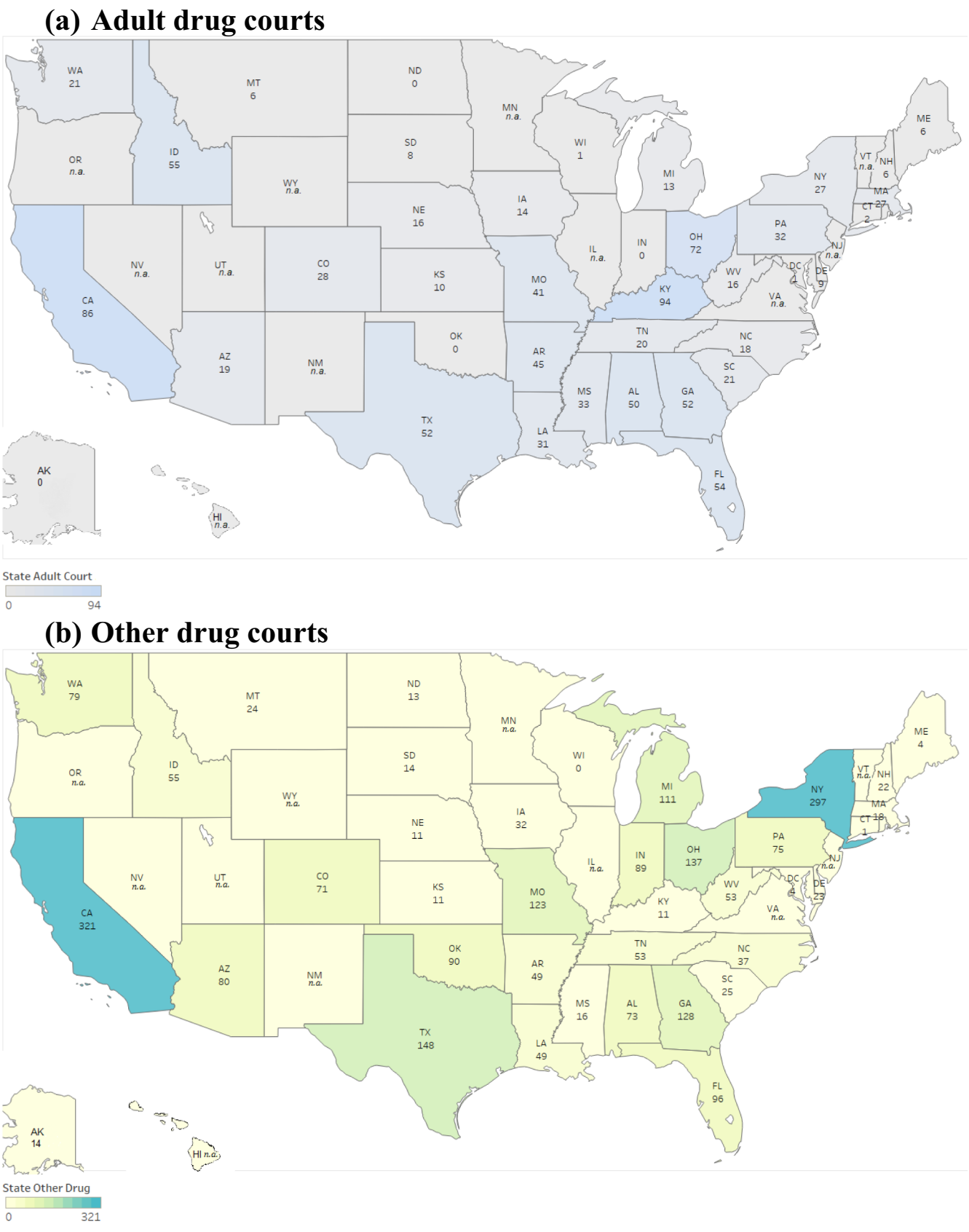

Fig. 1. Drug treatment court programs in the United States.

Table 1
Drug courts and MOUD-related physician payments.

Factor	Model 1 Outcome: likelihood to receive DTP payments (logit model)		Model 2 Outcome variable: DTP payments (OLS model)	
	Odds ratio	95% CI	Marginal Effect (Change in %)[a]	95% CI
Drug court presence				
No drug courts	1 [Reference]			
Any drug courts	1.616***	(1.402 to 1.862)	62.96***	(45.25 to 82.84)
Opioid overdose mortality, Rx rates, and access to SUD treatment				
Opioid-related deaths/100 K residents	1.012***	(1.006 to 1.019)	1.74***	(1.33 to 2.15)
Retail opioid prescriptions dispensed per 100 persons	1.005***	(1.003 to 1.007)	−0.07	(−0.20 to 0.05)
No. DATA waivers/100 K residents	1.075***	(1.063 to 1.087)	6.40***	(5.43 to 7.37)
No. substance abuse treatment facilities/100 k residents	0.971**	(0.954 to 0.989)	−2.16***	(−2.98 to −1.33)
Socio-demographic characteristics				
Primary physicians per 100 K residents	1.004*	(1.001 to 1.007)	0.46***	(0.23 to 0.68)
Rural population (%)	0.956***	(0.953 to 0.960)	−3.14***	(−3.37 to −2.90)
Household income ($1000)	1.041***	(1.033 to 1.050)	3.93***	(3.31 to 4.55)
Non-Hispanic African American population (%)	0.992*	(0.985 to 0.998)	−0.11	(−0.60 to 0.38)
Hispanic American population (%)	0.986***	(0.979 to 0.993)	−1.65***	(−2.11 to −1.19)
Asian to Pacific Islander, American Indian population (%)	1.042***	(1.024 to 1.060)	2.24***	(1.43 to 3.05)
County population (100 K residents)			26.25***	(18.78 to 34.19)
Dep. Variable Mean	0.34		873.13[b]	
Dep. Variable SD	0.47		8968.95[b]	
Observations (county x year)	9640		9640	
Year dummies and state dummies	Yes		Yes	
Pseudo-R squared	0.42[c]		0.57	

[a] Semi-elasticities were reported instead of regression coefficients.
[b] Dollar amount of payments.
[c] McFadden's pseudo-R squared was reported for the logit model.
* P < 0.05.
** P < 0.01.
*** P < 0.001.

Table 2
Adult Drug Courts versus Other Drug Courts.

Factor	Model 1 Outcome: likelihood to receive DTP payments (logit model)		Model 2 Outcome variable: DTP payments (OLS model)	
	Odds ratio	95% CI	Marginal Effect (Change in %)[a]	95% CI
Drug court presence				
No drug courts	1 [Reference]			
Adult drug courts	1.691***	(1.432 to 1.996)	73.73***	(51.13 to 99.72)
Other drug courts	1.527***	(1.265 to 1.844)	50.49***	(30.14 to 74.02)
Opioid overdose mortality, Rx rates, and access to SUD treatment				
Opioid-related deaths/100 K residents	1.013***	(1.006 to 1.019)	1.74***	(1.33 to 2.16)
Retail opioid prescriptions dispensed per 100 persons	1.005***	(1.003 to 1.007)	−0.07	(−0.20 to 0.05)
No. DATA waivers/100 K residents	1.075***	(1.062 to 1.087)	6.39***	(5.42 to 7.37)
No. substance abuse treatment facilities/100 k residents	0.971**	(0.954 to 0.988)	−2.18***	(−3.00 to −1.35)
Socio-demographic characteristics				
Primary physicians per 100 K residents	1.004*	(1.001 to 1.007)	0.46***	(0.23 to 0.68)
Rural population (%)	0.956***	(0.953 to 0.960)	−3.13***	(−3.37 to −2.90)
Household income ($1000)	1.041***	(1.033 to 1.050)	3.93***	(3.31 to 4.56)
Non-Hispanic African American population (%)	0.992*	(0.986 to 0.999)	−0.09	(−0.58 to 0.40)
Hispanic American population (%)	0.986***	(0.979 to 0.993)	−1.65***	(−2.11 to −1.18)
Asian to Pacific Islander, American Indian population (%)	1.041***	(1.024 to 1.060)	2.26***	(1.45 to 3.07)
County population (100 K residents)			26.21***	(18.75 to 34.13)
Dep. Variable Mean	0.34		873.13[b]	
Dep. Variable SD	0.47		8968.95[b]	
Observations (county x year)	9640		9640	
Year dummies and state dummies	Yes		Yes	
Pseudo-R squared	0.42[c]		0.57	

[a] Semi-elasticities were reported instead of regression coefficients.
[b] Dollar amount of payments.
[c] McFadden's pseudo-R squared was reported for the logit model.
* P < 0.05.
** P < 0.01.
*** P < 0.001.

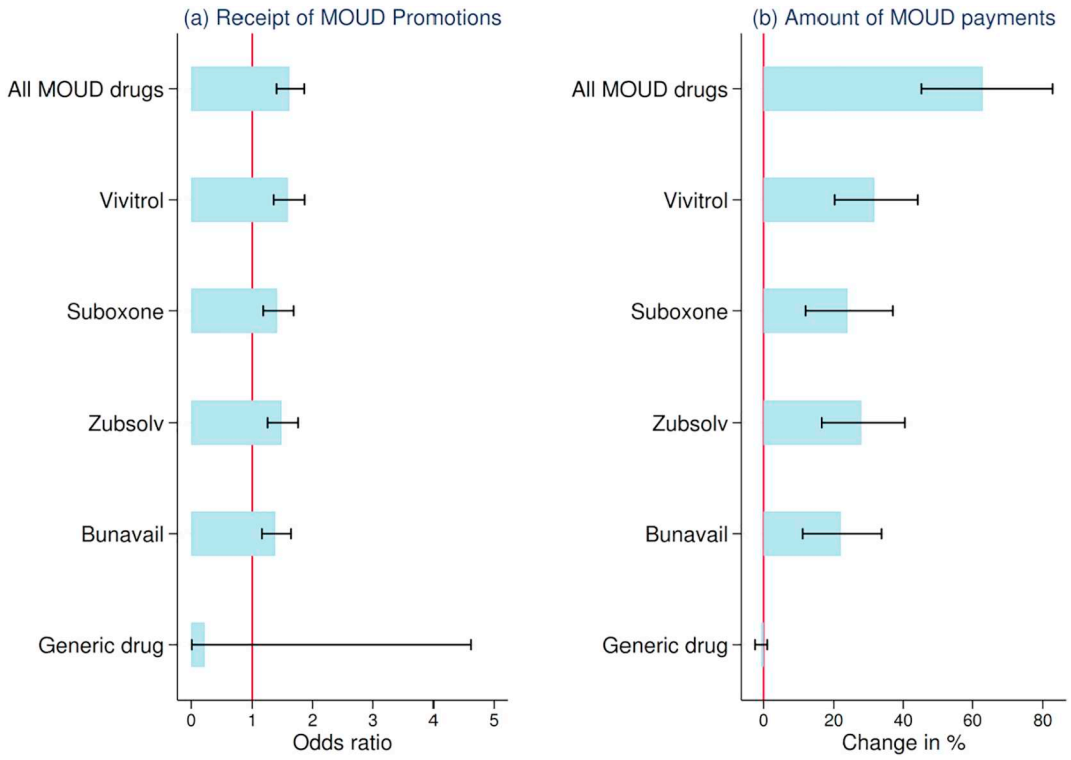

Fig. 2. Pharmaceutical payments and presence of drug courts.

likelihood of receiving any payment, we found positive associations between the presence of adult drug courts and amount of payments for Vivitrol, Suboxone, Zubsolv, and Bunavail, but not for generic buprenorphine-naloxone.

3.2. Sensitivity analyses

We provided two additional analyses based on alternative assumptions for the "missing year" drug courts (alternately assigning all 528 "missing year" drug courts to have opened either in 2014 or 2017) in Fig. 3. These results closely mirror the baseline results (shown in Fig. 2).

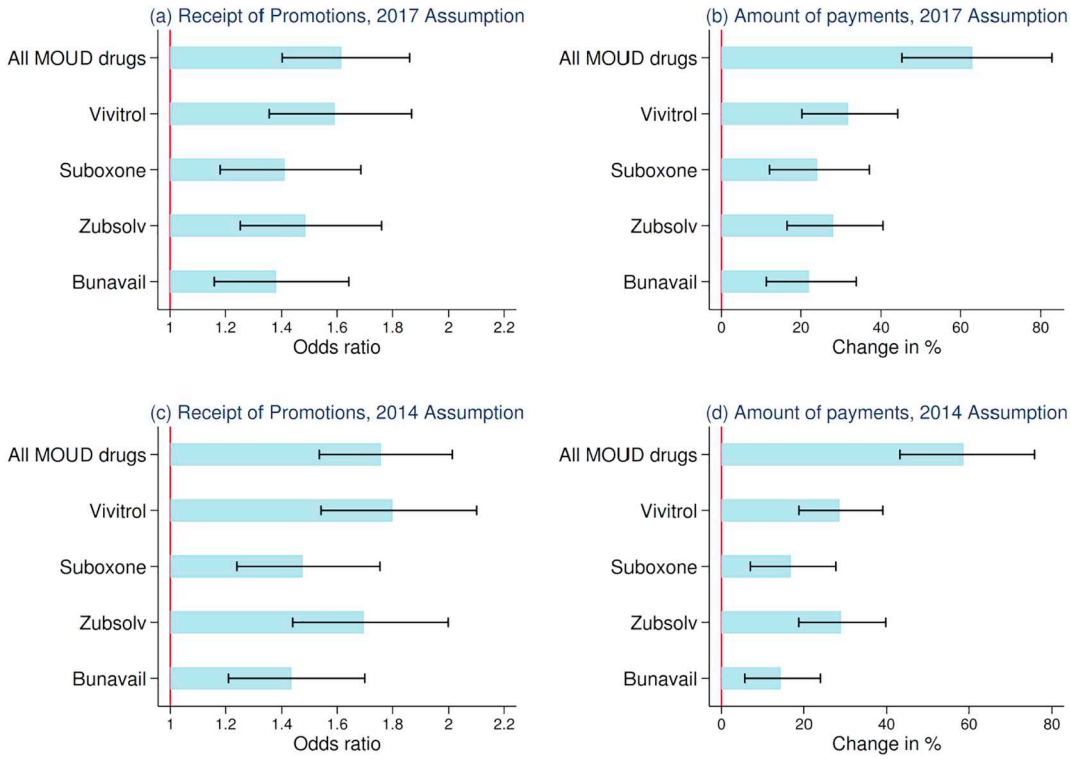

Fig. 3. Two assumptions of "missing year" drug courts.

Overall, these results reinforce the positive associations between drug courts and MOUD-related provider-directed advertising.

4. Discussion

Although our study did not examine marketing efforts towards drug courts directly (as such data is not publicly available), we did examine publicly-reported payments by MOUD manufactures to physicians in counties with and without drug courts. The presence of a drug court appears associated with manufacturer promotional activities in a geographic area. However, we caution that our study was ecological and not causal in nature.

We hypothesized a higher rate of promotional activities for extended-release naltrexone in areas with drug courts as compared to areas without drug courts, because drug court participants may represent a higher share of prescribers' patients in these areas; and manufacturers may know that drug court policies frequently forbid buprenorphine access (Matusow et al., 2013). However, our study found no significant difference between payments by the manufacturer of Vivitrol and manufacturers of Zubsolv, Bunavail, and Suboxone (oral forms of buprenorphine).All four manufacturers appear more likely to target marketing efforts towards physicians in counties with drug courts than counties without drug courts. Therefore, it is possible that counties with more severe drug problems are simply more likely to endorse both drug courts and MOUD as potential solutions. This interpretation is bolstered by the fact that we found counties with higher rates of opioid-related deaths, an indicator of severity of drug problems, received more MOUD manufacturer payments. However, the county-level opioid-related death rate may not fully capture the severity of drug problems in our baseline regression.

Our ecological association between drug courts and promotions cannot explain whether any MOUD manufacturers have targeted drug court staff with marketing activities, such as educational trainings. We can only show whether MOUD manufacturers have targeted prescribers in areas with drug courts who themselves may have a professional referral relationship with drug court staff. Nevertheless, our results suggest that media attention may have been one-sided by focusing on Alkermes' marketing activities, since we found no significant difference between Alkermes' promotional activity and some buprenorphine manufacturers' activities towards prescribers in counties with drug courts. On the other hand, promotional activities towards drug court staff, even if they occur, may not be associated with promotional activities towards prescribers in the area. Therefore, future research should directly examine MOUD manufacturers' marketing towards drug court staff, such as by surveying court staff about their experiences rather than relying on proxy measures.

Not surprisingly, the association between payments to physicians and the presence of an adult drug court was larger than the association between payments to physicians and the presence of other forms of drug courts, such as DUI courts, family drug courts and juvenile drug courts. Even though studies suggest that MOUD is effective in adolescent populations (Hadland et al., 2018; Subramaniam et al., 2013), since buprenorphine and naltrexone were FDA-approved for adult populations, physicians may be wearier of prescribing MOUD for youth than for adults (Saloner et al., 2017); therefore, drug court staff may find it difficult to refer non-adult participants to local MOUD prescribers. Drug court staff may also be less likely to refer family drug court participants, as opposed to adult drug court participants, to MOUD prescribers, because drug court staff may fear accidental poisoning among children in the household of a family drug court participant. Finally, DUI courts primarily include participants with alcohol use disorder, for which naltrexone is the only effective MOUD; therefore, the presence of an adult drug court is more likely an indicator of MOUD demand than is a DUI court.

We were surprised, however, to find that the rate of SAMHSA waivered physicians was not associated with MOUD manufacturer payment, because a waiver may indicate a physician's pre-existing interest in treating patients with OUD and interest in prescribing MOUD. Previous studies have found significant resistance among physicians to treating this health condition and to prescribing MOUD (Andraka-Christou, 2017; Huhn & Dunn, 2017; Hutchinson, Catlin, Andrilla, Baldwin, & Rosenblatt, 2014). However, our dataset of SAMHSA waivered physicians did not include the number of physicians who had recently prescribed buprenorphine (Thomas et al., 2017); and many waivered physicians do not prescribe buprenorphine despite the ability to do so, indicating less physician interest in MOUD than might appear at first glance. The presence of waivered physicians is also an imperfect measure of physician interest in treating patients with OUD, because extended-release naltrexone can be prescribed without a waiver.

We also found that more primary physicians, lesser rural populations, higher median household income, and a smaller proportion of Hispanics and African Americans are associated with MOUD manufacturer payments. Each of these county level characteristics are indicative of economic resources and thus potentially more profitable counties for MOUD manufacturers to target. Additionally, MOUD manufacturers may avoid areas with minority populations, because they assume that minority populations have greater demand for Opioid Treatment Programs (Krawczyk, Negron, Nieto, Agus, & Fingerhood, 2018), where methadone is dispensed, than office-based buprenorphine or naltrexone treatment. On the other hand, areas with minority populations might have greater demand for office-based MOUD if such treatment were more readily accessible, including as a result of MOUD manufacturers promoting it to office-based physicians.

The gap between minority and non-minority utilization of office-based buprenorphine or naltrexone treatment is problematic (Krawczyk et al., 2018), because office-based treatment may be less stigmatizing than methadone treatment in Opioid Treatment Programs (Fiellin, Rosenheck, & Kosten, 2001; Oliva, Maisel, Gordon, & Harris, 2011). Additionally, office-based treatment with buprenorphine or naltrexone is more flexible than methadone treatment in Opioid Treatment Programs, especially for people with employment or household duties who cannot attend a clinic daily (Fiellin et al., 2001; Oliva et al., 2011).

Even though we found an association between promotional activities to MOUD prescribers and the presence of a drug court at the county level, we are unable to ascertain whether promotional activities occurred towards criminal justice administrators within the drug courts. No state or federal law requires pharmaceutical companies to report marketing efforts towards non-prescribers, like judges, court program directors, and case managers, even if these individuals make decisions about whether court participants can access MOUD. One study found that pharmaceutical marketing towards judges plays a role judges decisions about whether to permit court participants access to MOUD; but that study was qualitative, had a small sample size, and was restricted to the state of Indiana (Andraka-Christou, 2017). State or federal law restricting communication between pharmaceutical companies and criminal justice administrators could run afoul of the First Amendment, which has been interpreted to protect certain types of commercial speech(Virginia State Pharmacy Board v. Virginia Citizens Consumer Council, 1976); but policy makers could require criminal justice administrators to disclose the nature and date of such conversations in a public database, much the same way as prescribers must disclose receipt of promotional funds from pharmaceutical companies. Finally, even if speech between court staff and pharmaceutical companies is not restricted, states and federal laws could make court funding contingent on staff allowing participants to access any MOUD recommended and prescribed by a qualified practitioner. Indeed, SAMHSA has already instituted such a policy (Davies, 2015), but many drug courts receive little or no federal funding (Andraka-Christou, 2017), suggesting that funding levers are important at the state and local levels.

Our study has several strengths. To our knowledge, it is the first to examine the association between MOUD manufacturers' marketing activities and the presence of local drug courts. Additionally, we

examined potential differences in marketing activities between different types of MOUD manufacturers' (i.e. agonist and antagonist manufacturers), even though the media has recently focused on the behavior of an antagonist manufacturer.

Despite these strengths, our conclusions are limited by the lack of data regarding direct marketing to drug courts. Instead, we use the level of physician payments to examine the relationship between MOUD marketing and drug courts. This decision is justified by the fact that drug court staff rarely include physicians (Andraka-Christou, 2017), so referrals for medication must be made to providers outside of the drug court. However, we acknowledge that many other factors beyond the presence of drug courts may contribute to the level of physician payments in a county, and we try to control for these factors. Missing data in the NDCRC dataset of drug court programs is another limitation of this study. Particularly, 26.9% of drug courts (928 programs) and 17.7% of adult/family treatment drug courts (223 programs) had missing values in implementation year or ZIP code. Therefore, the finding on the effects of adult/family treatment courts, which indicates stronger associations with MOUD-related physician payments than the effects of any drug courts, is more reliable.

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