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Pronounced State-Level Disparities in Prescription of Cannabinoids to Medicaid Patients

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Abstract

Introduction: Dronabinol is approved in the USA for chemotherapy-induced nausea as well as vomiting and HIV-induced anorexia, while cannabidiol is primarily approved for childhood epileptic disorders Lennox-Gastaut and Dravet syndrome. The use pattern for these prescription cannabinoids in the USA is unknown. This study examined Medicaid claims for two FDA-approved prescription cannabinoids, dronabinol and cannabidiol, approved in 1985 and 2018, respectively, from 2016–2020 to better understand the pharmacoepidemiologic trends and distribution of these drugs in US Medicaid amidst the increasing use of non-pharmaceutical formulations of cannabis. ***Methods:*** The longitudinal study analyzed Medicaid prescription claims that were calculated by extracting the prescriptions on a state level from 2016 to 2020 for two cannabinoids, dronabinol and cannabidiol, where outcomes over each year were calculated. Outcomes were (1) the number of prescriptions for each state corrected for the number of Medicaid enrollees and (2) dronabinol and cannabidiol spending. Spending refers to the amount reimbursed by the state Medicaid program. ***Results:*** Dronabinol prescriptions per state decreased by 25.3% from 2016 to 2020, while cannabidiol prescriptions increased by 16,272.99% from 2018 to 2020. The spending on these drugs parallels that of their prescription trend with a 66.3% decrease in reimbursement for dronabinol ($5.7 million in 2020), whereas cannabidiol increased by +26,582.0% ($233.3 million in 2020). Dronabinol prescriptions, when corrected for the number of enrollees, in Connecticut were 136.4 times larger than in New Mexico, and seventeen states had zero prescriptions. Idaho's prescriptions of cannabidiol (27.8/10,000 enrollees) were significantly elevated relative to the national average and were 15.4-fold higher than Washington, DC (1.8/10K enrollees). ***Conclusions:*** The prescriptions of pharmaceutical-grade tetrahydrocannabinol decreased while those of cannabidiol increased. This study also identified pronounced state-level variation in cannabinoid prescribing to Medicaid patients. State formularies and prescription drug list variation may contribute to the drug reimbursements in Medicaid, though further research is needed to identify the health policy or pharmacoeconomic origins of these disparities.

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Introduction

Dronabinol is synthetic tetrahydrocannabinol (THC) that has been US Food and Drug Administration (FDA) approved since 1985 to treat HIV/AIDS-induced anorexia and to treat patients who do not respond to conventional anti-emetics from the nausea and vomiting of chemotherapy [1, 2]. Dronabinol activates the cannabinoid CB_1 receptor, stimulating appetite and provoking an anti-emetic response by reducing the emetic effects of endogenous neurochemicals like dopamine and serotonin [1, 2]. Over half of chemotherapy cycles adversely affected the quality of life for patients by inducing undesirable effects including nausea, vomiting, anorexia, nutrient depletion, and metabolic imbalances. By using dronabinol alone or in combination with conventional anti-emetics like ondansetron and prochlorperazine, randomized clinical trials concluded that dronabinol helped prevent nausea and vomiting episodes [2]. Prescription THC activates the CB_1 to combat weight loss and wasting syndrome from HIV by increasing appetite [1]. The causes of weight abnormalities are hypothesized to be due to several factors, including reduced caloric intake from depression, increased financial difficulties and opportunistic infections, and aggravated metabolic dysfunctions. Dronabinol helped HIV-positive patients increase their daily caloric intake by consuming more meals throughout the day [3].

A randomized double-blind study demonstrated that dronabinol can also treat neuropathic pain associated with multiple sclerosis [4]. Although there were adverse reactions, including restlessness, irritability, sleep interference, decreased appetite, and drug-dependence, this cannabinoid showed promising long-term therapeutic effects in treating neuropathic pain with little to no signs of abuse or dependence. Dronabinol was changed from schedule II (high abuse potential) to schedule III (low to moderate abuse potential) in 1998 due to its gradual onset of action, dysphoria, and other factors [5]. Considerations regarding drug-drug interactions, contraindications, use in specific populations, and other unfavorable effects should be carefully considered. The US FDA [6] indicated that dronabinol could affect the metabolism of other drugs by inducing or inhibiting cytochrome P450 enzymes (3A4 and 2C9), aggravating mental and/or physical symptoms in patients with neuropsychiatric disorders, inducing fetal harm in pregnant women, causing lactating issues, and exacerbating the neuropsychiatric problems of elderly patients because they are more sensitive to this medication.

The only FDA-approved cannabidiol (CBD) formulation (Epidiolex) has gained recent popularity since its approval by the FDA on June 25, 2018, as the first plant-derived, purified pharmaceutical-grade CBD in the USA to treat patients ≥1 year old with Dravet Syndrome (DS) or Lennox-Gastaut Syndrome (LGS) which are types of childhood medically refractory epileptic disorders [7, 8]. This drug was initially placed in schedule V, and in April 2020, it was descheduled entirely [9, 10]. Four randomized, double-blind, placebo-controlled clinical trials were done at 58 sites in Europe and the USA to address the efficacy and safety of CBD in treating LGS and DS with 550 patients aged 2–55 [11]. The GWPCARE1 trial showed a statistically significant decrease in the number of seizures in individuals with DS with an improved quality of life, while the GWPCARE 3 and 4 trials demonstrated a statistically significant dose-dependent effect on reducing the number of seizures in individuals with LGS, with approximately half of patients demonstrating ≥50% reduction in seizures [7]. The study concluded that CBD should be used as an adjunct with other antiepileptic medications to combat DS and LBS. The drug-drug interactions, however, must be carefully considered as CBD inhibits CYP2C8, CYP2C9, CYP2C19, UGT1A9, and UGT2B7, and there are dose-dependent increases in adverse effects from the adjunct therapy including lethargy, somnolence, fatigue, nausea, vomiting, and increased liver enzymes and frequency of upper respiratory infections [12].

The US FDA specified that the efficacy and the safe use of prescription CBD have led to its approval in 2020 to treat another epileptic disease called tuberous sclerosis, a rare genetic disorder that causes benign tumors to grow in the brain and other parts of the body, resulting in various symptoms including seizures, developmental delays, and other abnormalities [13]. Although the benefits and the safety of the drug are promising as indicated by the results of the multicenter clinical trials, further investigation is still needed before unqualified endorsements for long-term usage are made due to limited data on drug-drug interactions, its reproductive adverse health effects, and other problematic adverse effects [7]. The mechanism in which CBD induces anti-seizure effects remains unknown, but it is theorized to alter neurochemicals, such as serotonin, gamma-aminobutyric acid, t-type calcium channels, and N-methyl-D-aspartate by binding to CB_1 and CB_2 receptors. CB_1 is most dense in the basal ganglia, cerebellum, cortex, and hippocampus, which contributes to diseases affecting neurological conditions related to altered brain reward mechanisms, processes of learning and memory, as well as mood and anxiety

disorders, whereas CB_2 is present primarily in immune and hematopoietic systems, so activation does not cause psychoactive effects [14]. CBD may interact with several signaling systems including the Transient Receptor Potential Vanilloid type 1 (TRPV-1) to induce anticonvulsant effects [15].

Since their approval, dronabinol and CBD have also been examined for various off-label uses [1, 7, 16]. However, there is currently a lack of information about their use patterns in the USA. Although prescription drugs have tightly regulated quality control, many states have liberalized their laws to increase the availability of non-prescription formulations of both THC and CBD. This study analyzed the prescriptions for dronabinol and CBD throughout the USA from 2016 to 2020 for Medicaid patients and quantified their state-level variation to understand the pharmacoepidemiologic trend and distribution of these drugs in US Medicaid amidst the increasing availability of other cannabis products.

Materials and Methods

Study Design and Data Sources

The national and state-level number of prescriptions for CBD (Epidiolex) and dronabinol (Marinol, Syndros) were obtained from Medicaid [17, 18] for 2016–2020 (online suppl. Table 1; for all online suppl. material, see https://doi.org/10.1159/000531058). Nabilone prescriptions were not present in the database from 2016–2020 and were not analyzed. This period was selected to include 5 years of recent information. The year 2020 was chosen as the end period for analysis because it was the last year for which full drug data were available when analysis was completed (3/2022). The Medicaid State Drug Utilization database captures outpatient drug data for every state, as well as Washington, DC, which are covered under the Medicaid Drug Rebate Program. State Medicaid programs who participate in this program are required to submit data quarterly to the Centers for Medicare and Medicaid Services (CMS), which include number of prescriptions filled, package size, units reimbursed, reimbursement, and National Drug Code (NDC) numbers for each drug at the state level by year and quarter [17]. Medicaid is a series of joint federal and state-administered and funded public insurance programs and plans, where the federal level CMS sets standards for coverage and reimbursement and are implemented by states [19]. CMS has collected and publicly reported monthly Medicaid enrollment at the state level since 2014. Medicaid enrollment for each state is available through the Medicaid Enrollment Data website [19] (online suppl. Table 2).

Measures

The mean number of prescriptions per state for each cannabinoid from 2016 to 2020 was determined. This type of analysis measures the number of prescriptions per enrollee for each state for the two cannabinoids from 2016 to 2020. The numerator refers to the number of prescription claims from Medicaid at state level for each year 2016–2020. The denominator accounts for the number of enrollees in Medicaid/CHIP for each of the years mentioned. Enrollment denominator differs in each year from 2016 to 2020 as the number of Medicaid enrollees is different. We selected the number of enrollees on December for each year as this represents the end of the year (i.e., "2019 Medicaid Enrollee as of Dec. 2019, etc.). Finally, the total drug reimbursement was obtained.

Data Analysis

The analyses were (1) heat maps, which displayed the prescriptions/enrollee for each state, were generated for the 50 states and Washington, DC, for both cannabinoids [20]; (2) total ratio of highest to lowest (non-zero) prescriptions per state, corrected for the number of Medicaid enrollees in 2020 in the USA with states outside a 95% confidence interval (mean ±1.96 *SD) interpreted as statistically significant ($p < 0.05$); (3) the average total number of prescriptions of both cannabinoids from 2016 to 2020 among all the states and the population corrected prescriptions for both cannabinoids at the state and national levels. Mean prescriptions were calculated by averaging the prescriptions per number of enrollees for each cannabinoid. Confidence interval of 95% was determined from the z score of 1.96. We identified states with prescriptions/enrollees with ≥1.96 standard deviations different from the mean as significant; (4) the annual total drug reimbursement ($) from 2016 to 2020 for both cannabinoids. The data analyses and figures were completed using GraphPad Prism v 9.3.1.

Results

Tetrahydrocannabinol

Dronabinol average prescriptions per state showed a gradual decrease (−25.3%) from 2016 to 2020 (online suppl. Fig. 1a). Similarly, when prescriptions were corrected for the number of enrollees, there was a 31.6% decrease (online suppl. Fig. 1b). Total spending on dronabinol decreased 66.3% from $17.1 million in 2016 to $5.7 million in 2020 (online suppl. Fig. 2).

Dronabinol prescription in the top state, Connecticut (180.0 per 100K Medicaid enrollees), was 136.4-fold greater than that of the lowest non-zero state (New Mexico = 1.3, Fig. 1). CT, Nebraska, Missouri, and Maine had a greater number of prescriptions (>1.5 SDs) than the national mean. One-third of states (17) had no dronabinol prescriptions including a cluster (NV, ID, MT, WY, ND, SD, IO, WI) in the north-central USA.

Cannabidiol

CBD average prescriptions per state (uncorrected) showed a pronounced (+16,272.99%) increase since its approval in 2018 until 2020 (online suppl. Fig. 1c). Similarly, the number of prescriptions when corrected for the number of enrollees showed a substantial increase (+14,496.77%) during this interval (online suppl. Fig. 1d).

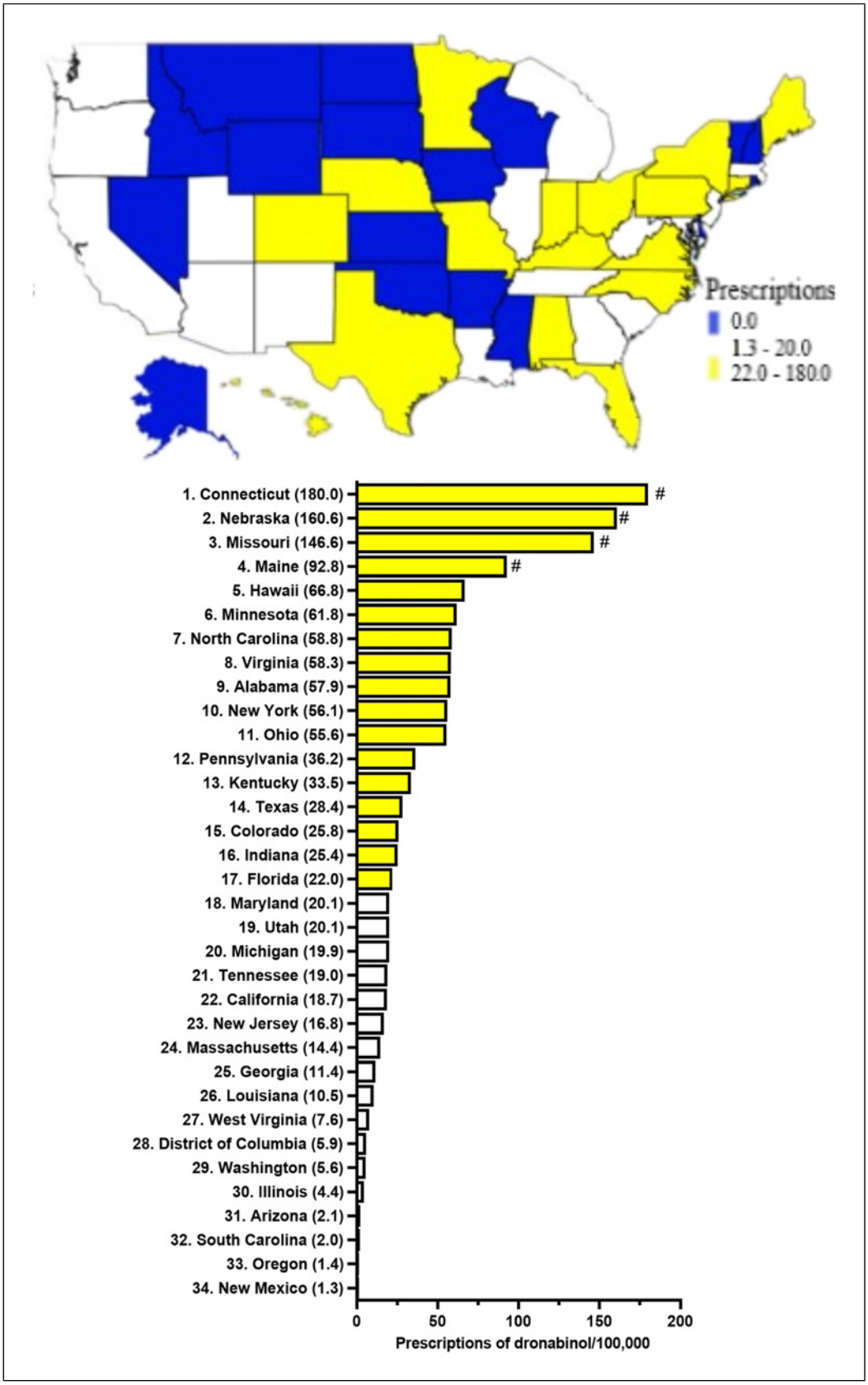

Fig. 1. Dronabinol prescriptions per 100,000 Medicaid enrollees. Heatmap (top) and ranked (bottom) in 2020. States outside #1.50 standard deviations from the mean. Seventeen states including DC with 0 prescriptions are not shown on the bar graph.

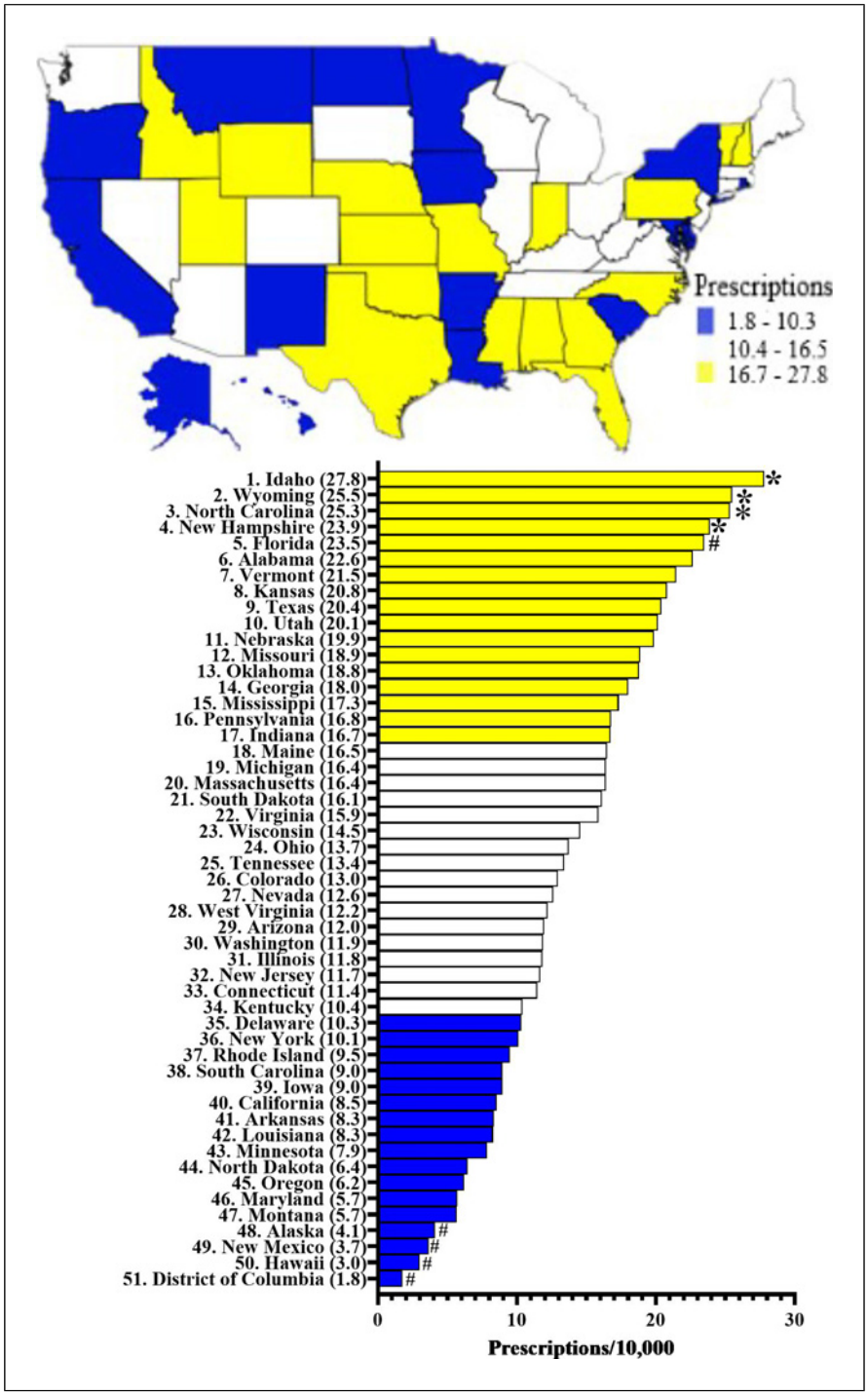

Fig. 2. Cannabidiol prescriptions per 10,000 Medicaid enrollees. Heatmap (top) and ranked (bottom) in 2020. States outside *1.96 or #1.50 standard deviations from the mean.

Medicaid spending also demonstrated an exponential increase of 26,581.98% from $874,370.82 in 2018 to $233,299,416.18 in 2020 (online suppl. Fig. 2).

Figure 2 shows a 15.4-fold difference in the population (i.e., number of enrollees) corrected prescriptions of CBD between Idaho and DC in 2020. Idaho, Wyoming, North Carolina, and New Hampshire demonstrated significantly greater prescribing than the average. Florida showed greater (>1.5 SD), while Alaska, New Mexico, Hawaii, and DC had lower (<1.5 SD) prescribing than the average.

Discussion

There was a 25% decrease in dronabinol prescriptions between 2016 and 2020 and an increase in CBD prescriptions of 16,273% from 2018 to 2020, with pronounced state variation in prescriptions to Medicaid patients. Dronabinol can be used alone or in combination with other drugs to treat chemotherapy-induced nausea and vomiting, HIV-associated anorexia, and chronic pain since its approval in 1985 [21], whereas CBD has specifically been proven to work in adjunct with other antiepileptics to treat rare epileptic disorders, specifically Lennox-Gaustaut and Dravet syndromes since its approval in 2018 [7]. Understanding the distribution of the two medical cannabis drugs provides a novel insight into their pharmacoepidemiology, especially with the rising attention in the use of cannabis to combat various medical conditions [16].

The sizeable state-level variation in dronabinol prescriptions may be explained by various factors including differing Medicaid Preferred Drug List (PDL) policies [22]. The lower number of dronabinol prescriptions compared to CBD might be because dronabinol is a schedule III drug, is less likely to be indicated as a preferred drug in the Medicaid PDL or included in it, and this cannabinoid has step therapy policies in some states [10, 23, 24]. PDLs are generally implemented by states to reduce prescription costs, but the application of this policy varies among the states depending on factors such as the possible effects of drug restrictions on the quality of care, issues between cost-savings and quality of care, and the administrative costs related to the program [25, 26]. The inclusion of certain drugs into the PDL is specifically determined by the negotiation of the price rebates between the manufacturer and the state Medicaid programs [27]. Step-through parameters like the required use of 5-HT_3 receptor antagonists for cancer-associated nausea and vomiting prior to approval of dronabinol might explain the larger variability of dronabinol prescriptions among the states [28].

Similarly, the pronounced increase in CBD prescriptions from 2018 to 2020 may be explained by increased incorporation into the PDL of some states [9, 24, 29] and its de-scheduling in 2020. The high population-corrected CBD prescriptions in Idaho and Wyoming might be explained by the late or lack of Medicaid expansion, especially since states that have expanded Medicaid enable individuals who are under 65 to qualify for the program if their income is up to 138% of the federal poverty level [27]. Idaho expanded its Medicaid program in 2020, whereas Wyoming has not [28]. A previous study has shown that the prevalence of epilepsy is higher in low-income Americans, individuals with pre-existing disabilities, and comorbid conditions than in the general population [30]. Therefore, states that were late to expand or still have not expanded may have increased use of CBD, specifically in populations with poorer health and lower income than states who have expanded Medicaid.

In addition to the differing policies, regulations, the varied knowledge of the use, benefits, and adverse effects of these cannabinoids combined with the negative stigma of the substance and incomplete scientific evidence on the medication's safety and efficacy may also contribute to the varying amounts of prescription claims for dronabinol and CBD [31]. Given that CBD is a relatively new FDA-approved drug, prior authorizations, step therapy, and other regulations may limit its inclusion on state PDLs, contributing to the state-level variations.

The drug reimbursement for Medicaid parallels that of the temporal trend in prescriptions for both cannabinoids. The Red Book from IBM Micromedex [32] is generally used as price benchmarks for drugs, and it lists the average wholesale price (AWP) and wholesale acquisition cost (WAC) of dronabinol as $4,242 and $1,213.8, respectively. The AWP and WAC are $1,848.00 and $1,540.00, respectively, for a 100-mL oral solution of Epidiolex. The annual price of CBD ($32,500) is non-trivial, although this is aligned with the cost of other antiepileptics [33]. The sales of non-pharmaceutical-grade CBD in the USA rose from $535 million in 2018 to $4.6 billion in 2020, and the growth is expected to rise to more than $20 billion by 2024–2025 [34, 35]. This greatly dwarfs the $233.3 million spent by the Medicaid program in 2020 for pharmaceutical-grade CBD.

Some limitations and future directions are noteworthy. These include findings that were applicable only to the 82 million patients served by the Medicaid program and analysis of the two FDA-approved cannabinoids. Future research with Medicare or privately insured US patients or in other countries is warranted. The Medicaid State Drug Utilization database provides timely information about prescribing, but further study with electronic medical records would be necessary to further characterize prescribing patterns in specific patient populations. As the approved indications for CBD are relatively rare (DS incidence is 1 per 22,000–40,900 [36], LGS was 4% of all cases of childhood epilepsy [37], tuberous sclerosis incidence ranges from 1 per 5,800 to 10,000 live births [38]), further research to characterize the off-label use of CBD may be informative. A cross-sectional study found that CBD has been highly used for reasons, including mental health, sleep, stress, and general health and wellbeing,

which may explain the prevalent use of these agents [39]. Pharmacoeconomic research may also be warranted that compares the patient-level cost for pharmaceutical vs. non-pharmaceutical-grade cannabinoids [40]. As the number of prescriptions was modest, particularly for dronabinol, relative to ubiquity of medical marijuana in the USA (5.5 million patients) [41], further qualitative research may be needed to better understand the decision-making process of health care providers and patients. Future directions may include correcting the number of Medicaid enrollees based on the indications of dronabinol and CBD that these were prescribed for.

In summary, the number of dronabinol prescriptions to US Medicaid patients showed a moderate decrease, while CBD demonstrated an exponential increase since its 2018 approval. There was also pronounced state-level variation in prescriptions of these cannabinoids. Further research needs to be completed to determine which factors including PDL account for these regional differences.

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Statement of Ethics

Procedures were approved as exempt by the IRB of the University of New England (#0821-09, approved September 21, 2021) and Geisinger. The research project was granted an exemption by the IRB from informed consent as the database is de-identified and publicly available.

Conflict of Interest Statement

BJP was part of an osteoarthritis research team (2019–2021) supported by Pfizer and Eli Lilly. His research is supported by the Pennsylvania Academic Clinical Research Center and the Health Resources Services Administration (D34HP31025). The other authors have no disclosures.

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Author Contributions

Brian J. Piper was responsible for the design of the project with contributions from Edward Liu and Kenneth McCall. Edward Liu was responsible for data collection, analysis, and writing the first version of the manuscript. All authors approved the final manuscript.

Data Availability Statement

Raw data are available at: https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html. Further inquiries can be directed to the corresponding author. A preprint was submitted to MedRxiv on April 6, 2022 and is available at: https://www.medrxiv.org/content/10.1101/2022.06.04.22275992v1.

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