

## **Title**

Community pharmacist preceptors and their knowledge, experience, and perceived intent to recommend cannabidiol products for patient use

## **Incentive Grant Category**

Residents and Their Preceptors

## **Introduction**

Cannabidiol (CBD) has gained popularity amongst medical professionals for its treatment potential in a plethora of health conditions, most prevalently in seizure disorders.<sup>1,2</sup> Unlike its counterpart delta-9-tetrahydrocannabinol (THC), CBD does not elicit psychoactive or euphoric effects, is not addictive, and has a mild side effect profile.<sup>3-7</sup> With these characteristics, CBD offers an enticing potential therapeutic alternative in diseases with poorly-tolerated drug therapies or resistance to current drug therapies. The National Institutes of Health (NIH) clinical trial database reflects the growing interest in CBD, listing over 550 current studies analyzing its use.<sup>8</sup>

Despite the increasing number of studies and multitude of anecdotal accounts on the therapeutic benefits of CBD, confusion and apprehension persist regarding its use.<sup>9</sup> Clinically, there is still much to learn about the use of CBD. The therapeutic benefit of CBD has been established in Lennox-Gastaut and Dravet syndromes as the prescription-strength oral solution Epidiolex®,<sup>10</sup> as well as in spasticity associated with multiple sclerosis as the prescription-strength oromucosal spray Sativex® (in a 1:1 ratio with THC).<sup>11</sup> However, robust clinical data is currently lacking in other disease states.<sup>7,9,10</sup> At this time, there are no universally accepted treatment or dosing guidelines for CBD. Additionally, non-prescription CBD products vary widely in strengths, dosage forms, and overall integrity.<sup>12,13</sup> Although studies have shown CBD to be well-tolerated, its use does bring risks of both pharmacodynamic and CYP-mediated drug interactions, as well as potential liver injury among other milder side effects.<sup>6,7,9,10</sup>

Outside of clinical aspects, there are a slew of discrepancies between and within state and federal laws involving CBD. To date, 17 states have passed legislation allowing the use of CBD products, while 33 states have legalized its parent product, *Cannabis sativa L.*, for either medicinal or recreational purposes.<sup>14,15</sup> The crucial factor in determining CBD's legal status is the source from which it is derived.<sup>16</sup> According to the Drug Enforcement Agency (DEA), CBD derived directly from *Cannabis sativa L.*, a Schedule I controlled substance, is also classified as Schedule I.<sup>17,18</sup> Paradoxically, the prescription CBD product Epidiolex®, which is derived directly from *Cannabis sativa L.*, was previously classified as Schedule V when it was first approved in June 2018 but has since been removed from the Controlled Substances Act as of April 2020.<sup>10,17,19</sup> CBD derived from *hemp* (cannabis containing  $\leq 0.3\%$  THC by dry weight) is not a controlled substance since the Agricultural Improvement Act of 2018 (Farm Bill 2018) removed hemp and hemp-derived products from the definition of cannabis.<sup>17,18</sup> Despite being marketed and commercially available, food products, beverages, and dietary supplements containing CBD, even when derived from hemp, are illegal under the Food Drug and Cosmetic Act, which prohibits introducing active ingredients in a drug product

that has been approved or publicly investigated into foods or supplements.<sup>18,20</sup> Topical products containing CBD derived from hemp are permissible as long as the products are not intended or marketed to have therapeutic effects.<sup>18,20</sup>

While there is much discussion and legislation around CBD, there is a paucity of data showing the involvement and beliefs of United States (US) healthcare providers on its use. Kogan et al<sup>21</sup> examines veterinarian's experience and perceptions of CBD use in canines, and Szaflarski et al<sup>22</sup> analyzes the knowledge and attitudes of neurologists, nurses, and hospital pharmacists on cannabis and cannabis-based therapies, including a select few items addressing CBD use for epilepsy. Outside of Szaflarski et al, no other studies have examined pharmacists' beliefs on CBD specifically, although a handful of studies have explored these concepts for medical cannabis.<sup>23,24</sup> Because prescription and non-prescription CBD products are available in pharmacies, community pharmacists in particular are positioned to have significant exposure to these products. Evaluating community pharmacy preceptors may yield beneficial and applicable data in this area. As the potential for cannabinoid medicines to be incorporated into school of pharmacy curricula increases, community pharmacy preceptors may be exposed to a high volume of questions from student pharmacists regarding CBD. Ensuring preceptors have appropriate knowledge and confidence on CBD products can also serve to benefit the development of student pharmacists. By surveying preceptors across the US, this study aims to provide a national snapshot of community pharmacy preceptors' CBD product experience, clinical and legislative CBD knowledge, and perceived intent to recommend CBD products for patient use. Gaps in preceptor knowledge and confidence identified by this study may be used to develop educational materials as well as shared resources on CBD for the community pharmacist population as a whole to utilize in the provision of optimal care for patients wishing to add CBD products into their medication regimens.

## **Objectives**

The primary study objective was to characterize community pharmacist preceptors' knowledge and experience with CBD products and their perceived intent to recommend those products for patient use. The secondary study objective was to identify desired resources for pharmacists on CBD products.

## **Methods**

### *Study Population and Respondent Recruitment*

The Purdue University Institutional Review Board approved this cross-sectional descriptive study in January 2020. The study population consisted of pharmacists 18 years of age or older who read English, maintained an active pharmacist license, currently practiced in a community pharmacy setting, and actively precepted for accredited schools of pharmacy in the US. Any pharmacist not meeting these criteria was excluded from the study. As of July 2019, there were 143 accredited schools of pharmacy in the US.<sup>25</sup> Extrapolating from American Association of Colleges of Pharmacy (AACCP) preceptor survey data from 2017, the total number of current preceptors is estimated to be around 60,000.<sup>26</sup> The proportion of preceptors practicing specifically in community pharmacies is unknown. In order to estimate a survey

response rate, recruited schools of pharmacy were required to report the number of active community pharmacy preceptors for their respective school prior to receiving the survey link for dissemination.

Respondent recruitment occurred in two phases: Phase I consisted of contacting each school of pharmacy's experiential education coordinator or equivalent to assess their school's willingness to participate in the study. Phase II consisted of experiential education offices disseminating the survey link to their respective community pharmacy preceptors via email. To reduce the risk of duplicate responses from pharmacists who precepted for more than one school of pharmacy, only one school in each state was selected for respondent recruitment. For each state, a randomly ranked list of schools of pharmacy was generated via random number generator in Microsoft Excel®. The first school on each randomly generated list per state was contacted for study recruitment. If the first school did not want to participate in the study or did not respond after three outreach attempts, remaining schools on the state's list were contacted in order until a school was recruited or until the Phase I recruitment period ended.

#### *Survey Development and Administration*

A 36-item survey, divided into five sections, was used to collect information on preceptors' demographics, CBD product experience, clinical and legislative CBD knowledge, and perceived intent to recommend CBD products for patient use. Prior to the first question of the survey, respondents were asked a screening question to ensure they met study inclusion criteria. If inclusion criteria were met, respondents could advance to the remaining survey questions. The first section contained six multiple-choice questions on general respondent demographics. The second section contained five multiple-choice questions on CBD product experience, including previous training or education on CBD as well as personal and professional interactions regarding CBD. The third section contained six knowledge questions on clinical and legislative issues pertaining to CBD. Clinical questions were developed from several resources including the Epidiolex® package insert, Micromedex®, and Lexicomp Online®. Legislative questions were based on current federal law and Food and Drug Administration (FDA) regulations. All knowledge items utilized a multiple-choice or select-all-that-applies format with "I don't know" as an answer option. The fourth section contained 15 perception questions to assess respondent intent to recommend CBD products. Perception questions were developed through the application of the Theory of Planned Behavior (TPB), which hypothesizes that the intent to perform a behavior is influenced by three primary factors: (1) attitude towards the behavior, (2) subjective norms, and (3) perceived behavioral control.<sup>27,28</sup> TPB suggests perceived control moderates the influence of attitude and subjective norms in the overall intention to perform a behavior, and generally intention increases with affirmative attitudes, subjective norms, and perceived control.<sup>27,28</sup> The survey contained four items measuring attitude towards the behavior, three items measuring subjective norms, five items measuring perceived behavioral control, and three items measuring overall intent. All perception questions were rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The fifth and final section contained two multiple-choice questions regarding confidence in knowledge of CBD legislation and specific disease states for which respondents would

be willing to recommend CBD products, as well as two open-ended questions regarding overall concerns with and resources for CBD products. A handful of survey items were adapted from previously published surveys with permission from study investigators. Five questions were adapted from the 28-item survey in Kogan et al (2019)<sup>21</sup> and three questions were adapted from the 27-item survey in Adeoye et al (2018).<sup>29</sup>

To assure quality and clarity of survey items, the survey was pilot-tested by six pharmacists and a senior medical science liaison. Pilot-testing feedback resulted in minor modifications prior to survey instrument finalization.

The survey instrument ([Appendix A](#)) was input into Qualtrics™, an online survey software tool, and administered electronically. Preceptors identified from the recruitment process were sent an email invitation with survey link by their respective school of pharmacy experiential education office or equivalent. Recruitment of schools of pharmacy (Phase I) began in December 2019 and concluded in January 2020 for a six-week duration. Initial survey dissemination (Phase II) occurred in January 2020 and concluded in April 2020 with one reminder email invitation, if permitted by the school, sent approximately halfway through the 12-week total survey duration. Respondents provided waived consent at the initiation of the survey. Participation was anonymous and voluntary, and respondents were able to withdraw at any point while completing the survey. After survey completion, correct responses to knowledge items were displayed and respondents had the choice to be redirected to an optional web-based gift card raffle as incentive for participation.

### *Data Analysis*

Data were downloaded from Qualtrics™ upon close of the survey. Prior to analyzing the aggregate data, the primary author reviewed each response to ensure inclusion criteria were met. Remaining aggregate response data were analyzed using Qualtrics™ and Microsoft Excel®. Descriptive statistics (percentages, means, medians, ranges, and standard deviations) were computed to summarize respondent demographics, CBD product experience, clinical and legislative CBD knowledge, and TPB perception items. “Select-all-that-apply” knowledge question responses were individually reviewed by the primary author and coded as “Correct” (all answers correctly identified) or “Incorrect” (some or none of the answers correctly identified). Qualitative analysis was completed by the primary author for the two open-ended, text-based items in section five of the survey to identify common themes in overall concerns with and desired resources for CBD. All responses analyzed for each question, regardless of survey completion, were included in the final results.

## **Results**

### *Respondents*

Of the 51 schools of pharmacy contacted throughout Phase I, 13 schools (25.5%) agreed and participated in the study. Based on reported preceptor numbers from each school, the survey was disseminated to an estimated total of 2,242 pharmacy preceptors. Of the 295 preceptors (13.2%) who responded to the survey, 272 were eligible to participate and held practice sites across 31 states. From the 272 eligible

study respondents, 236 completed the survey in its entirety, yielding an 86.8% completion rate. Respondents had a median age of 39 (range: 25-69) and a median of 13 total years of experience working in community pharmacy (range: 1-43). The majority of respondents held a PharmD degree (64.1%), practiced in the South (38.5%) or Midwest (33.9%) regions in the US, and worked in a chain (32.8%), independent (31.3%), or grocery store pharmacy (17.4%). (Table 1, Appendix B)

### *CBD Experience Items*

The majority of respondents (72.0%) reported never personally using a CBD product. Previous education on CBD was mixed, with 175 respondents (70.9%) reporting some type of education with or without personal research, 34 (13.8%) reporting only personal research, and 38 (15.4%) reporting no previous education or personal research. One-hundred and nineteen (48.4%) respondents reported selling CBD products in their pharmacies, with the most common products available being topical creams and lotions (85.7%), oral oils and tinctures (67.2%), and oral capsules and tablets (54.6%). (Table 2, Appendix B) Respondents reported having interactions about CBD most frequently with patients and pharmacy colleagues. Patient interactions were ranked as most common by 163 (65.99%) of respondents and second most common by 56 (22.7%); pharmacy colleague interactions were ranked as most common by 67 (27.1%) of respondents and second most common by 137 (55.5%). Although the frequency of specific interactions regarding therapeutic uses, adverse effects, and drug interactions of CBD were mixed, some level of interaction was reported by 89.1% of respondents for therapeutic uses, 74.9% for adverse effects, and 76.5% for drug interactions. While 66.0% of respondents reported being asked to recommend a specific CBD product, only 41.7% of respondents reported actually recommending a product for patient use. (Table 3, Appendix B)

### *Knowledge Items*

Respondent performance varied widely on both legislative and clinical knowledge items. The majority of respondents correctly identified that CBD derived from hemp is not a controlled substance (83.7%) and that state law does not supersede federal law (72.8%). However, only 54.4% of respondents correctly identified that food products and dietary supplements cannot legally contain CBD, while 20.9% answered incorrectly and 24.7% selected "I don't know." Likewise, for clinical questions, the majority of respondents correctly identified that CBD does not elicit euphoric effects (86.1%). However, only 4.6% of respondents correctly identified CYP 2C19 and CYP 3A4 as the most prominent CYP-mediated drug interactions with CBD, while 50.4% selected "I don't know." Of the 45.0% of respondents who answered incorrectly, 30.8% included CYP 2C19 as an answer, 64.5% included CYP3A4 as an answer, and 19.6% did not include either CYP 2C19 or CYP 3A4 as an answer. For the survey item addressing side effects of CBD, no respondents selected all five correct answer options (appetite suppression, diarrhea, increased suicidal ideation, liver injury, and somnolence and sedation) and 27.3% of respondents selected "I don't know." Of the 72.7% of respondents who answered incorrectly, 63.0% included somnolence and sedation as an answer, 27.7% included diarrhea, 17.2% included liver injury, 14.3% included appetite

suppression, and 5.0% included increased suicidal ideation. Euphoria was incorrectly identified as a side effect of CBD by 11.3% of respondents. (Table 4, Appendix B)

#### *Theory of Planned Behavior Items*

Table 5 (Appendix B) includes descriptive statistics for items related to TPB constructs. For items related to attitude, respondents reported that they believed CBD provided therapeutic benefit in many disease states (46.0% agree or strongly agree, 38.9% neutral) but felt that more research was needed before they would be comfortable recommending the use of CBD products (74.5% agree or strongly agree, 14.6% neutral). Most respondents disagreed that they felt comfortable counseling patients on CBD products (49.0% disagree or strongly disagree, 22.2% neutral) or recommending specific CBD products for patient use (56.1% disagree or strongly disagree, 20.1% neutral).

For items related to subjective norms, respondents reported evenly mixed feelings that patients in their community would be disappointed if they as the pharmacist did not recommend CBD products for patient use (31.8% agree or strongly agree, 33.1% neutral, 35.2% disagree or strongly disagree). The majority of respondents reported indifference in believing prescribers would approve of them as the pharmacist recommending CBD products for patient use (46.4% neutral). Many respondents reported knowing other pharmacy colleagues who recommended CBD products for patient use (49.0% agree or strongly agree, 19.3% neutral).

For items related to perceived behavioral control, most respondents disagreed that they had reliable resources on CBD products available in their pharmacies (57.8% disagree or strongly disagree, 14.8% neutral). Reflecting similar attitude items regarding comfort with counseling and recommending, most respondents disagreed that they have the necessary knowledge to counsel on (59.1% disagree or strongly disagree, 17.7% neutral) or recommend (61.6% disagree or strongly disagree, 14.4% neutral) specific CBD products for patient use. Respondents generally disagreed that they felt pressure from patients (62.5% disagree or strongly disagree, 16.0% neutral) or prescribers (79.8% disagree or strongly disagree, 14.8% neutral) to recommend CBD products.

Finally, for items related to overall intent, respondents reported positively trending intentions to counsel more patients on CBD products (42.2% agree or strongly agree, 41.8% neutral), but neutral trending intentions to recommend more CBD products for patient use (30.4% agree or strongly agree, 40.1% neutral, 29.5% disagree or strongly disagree). The majority of respondents reported planning to pursue additional education or training on CBD products (75.1% agree or strongly agree, 17.3% neutral).

#### *Additional Items*

When provided a list of disease states that they have recommended or would be willing to recommend the use of CBD, respondents most frequently selected pain (57.8%), anxiety (48.5%), arthritis (43.5%), inflammation (37.1%), and insomnia (35.9%). About a quarter of respondents (22.4%) selected “none of the above,” with one respondent stating in a free-response block under “Other” that their pharmacy policy is to tell

patients they cannot recommend CBD products for specific ailments. Respondents reported mixed levels of confidence in knowledge of their state-specific laws regarding CBD (24.8% not at all confident, 55.6% a little or moderately confident, and 19.7% very or extremely confident).

Several common themes regarding worries or concerns recommending CBD products emerged from the optional free text entries of 158 respondents (66.7%). The most common theme pertained to a lack of clinical evidence from robust research, with some respondents questioning if there was any true therapeutic benefit to be gained from using CBD. The next most common theme concerned the respondents' lack of knowledge about the products themselves, such as which dosage forms or which strengths to recommend, and several respondents cited a lack of available information to reference. Other common themes included safety concerns with CBD products, including drug interactions and long-term effects, as well as product quality and integrity concerns. A handful of respondents identified product legality as a concern, and a few specifically mentioned fear of liability if patients failed a drug test. Two respondents cited CBD's association with cannabis as a concern, and one respondent stated they were worried about "the type of customer [CBD] brings into [their] store."

## **Discussion**

To the best of the authors' knowledge, this study is the first to explore the knowledge and perceptions of CBD specifically in the community pharmacist population. This study contributes uniquely to the existing literature by providing a valuable baseline for what community pharmacists across the US know and think about CBD as well as what their professional experiences with CBD have looked like thus far.

In addition to specialty pharmacies in the US selling prescription Epidiolex® since 2018, major pharmacy retailers such as Walgreens and CVS have sold non-prescription, topical CBD products since 2019.<sup>30</sup> Roughly half of this study cohort reported selling CBD products in their pharmacies. Interestingly, respondents working in independent pharmacies were 8.4 times more likely to report CBD product sales than respondents working in other community practice sites. This difference is potentially attributed to the flexibility to implement changes quickly in the independent setting compared to traditional retail or hospital corporations. However, as this study's findings demonstrate, community pharmacists are having interactions about CBD even if their pharmacies do not sell any CBD products, with 89.1% of respondents reporting therapeutic discussions about CBD and only 48.4% reporting sales of CBD. This data emphasizes the need for pharmacists to be knowledgeable on this cannabis derivative.

Almost three-fourths of respondents reported receiving previous education on CBD, but only 5 respondents (2.03%) selected "pharmacy school classes" as a method of educational delivery. This potentially indicates a need for CBD as well as other cannabinoids to be incorporated into pharmacy school curricula. Previously published literature has also suggested this need, with one article by Abazia and Bridgeman<sup>31</sup> noting that pharmacist cannabinoid education during school has historically been limited to substance abuse courses without a focus on therapeutic properties. A study by

Berlekamp et al<sup>32</sup> analyzing 21 schools of pharmacy in the US found that 13 schools incorporated medical cannabis education into their curriculums, offered as part of a required course by five schools and an elective course by nine. The poor performance in this survey on knowledge items regarding drug interactions and side effects seems to support a lack of clinical education on CBD specifically. Furthermore, respondents generally felt they did not have the necessary knowledge to counsel on or recommend CBD products for patient use and reported discomfort in performing both activities. These findings present compelling evidence for additional cannabinoid education for pharmacists, and there appears to be no lack of desire in this cohort: the majority of respondents expressed affirmative intentions to pursue more CBD training.

Community pharmacists, and indeed all pharmacists, will continue to have significant exposure to CBD products as their popularity grows in and outside of the healthcare setting. Future research is needed to assess CBD knowledge, experience, and perceptions of pharmacists in other practice settings. Additionally, future studies examining the prevalence of CBD education in pharmacy schools as well as the impact of targeted educational interventions may be merited.

### **Limitations**

While this study provides beneficial information on community pharmacists' knowledge, experience, and perceptions of CBD, key limitations should be acknowledged. The overall survey response rate was just over 13%, and the authors recognize several potentially contributing factors. Only five of the 13 participating schools of pharmacy agreed to send a reminder email halfway through the data collection period. While one school reported "undeliverable" email bounce backs for two preceptors as a result of inaccurate email addresses, the total number of preceptors who never received the survey because of email challenges is unknown. Most prominently, the SARS-CoV-2 virus reached pandemic status in March 2020, halfway through the data collection period. Time to respond to surveys during the workday was likely significantly decreased due to the frenzy experienced in the healthcare system as a result of the pandemic. Out of respect for community pharmacists' time during the SARS-CoV-2 crisis, the research team chose not to request a final reminder email be sent during the last week of data collection. All of these factors likely reduced the overall survey response rate. While the survey reached preceptors with primary practice sites across 31 states, overall state representation was mainly limited to the 13 states in which each participating school of pharmacy was located. The West and Northeast regions of the US were the least well represented, comprised by 9.1% and 18.5% of respondents, respectively. As a result, the data collected by this study may not be representative of community pharmacists in these regions.

Although the survey created for this study was not validated and therefore did not have established psychometric estimates for reliability, validity, or sensitivity, study investigators worked diligently to ensure survey quality and integrity. Knowledge questions were formulated using reputable clinical resources and federal law, perception questions utilized TPB as a conceptual framework, and eight of the 36 survey items were adapted from previously published research. However, the authors

acknowledge a potential limitation with the results of one experience item regarding CBD interactions. To answer which group with which they most frequently discussed CBD, respondents had to drag-and-drop answer choices to order them from most common (1) to least common (5). The answer choices were listed in the following order by default for each participant: patients, pharmacy colleagues, prescribers, other healthcare providers, and other. The majority of survey results were ordered in this exact way, and it is unknown if the default ordering of the choices influenced these results.

**Conclusion**

The majority of community pharmacist preceptors in this cohort reported having clinical CBD interactions, most commonly with patients and pharmacy colleagues. Despite roughly half of the preceptors surveyed reporting the sale of CBD products in their pharmacies, the majority of respondents did not feel they had reliable resources available in their pharmacies on CBD, and most respondents were not comfortable counseling on CBD products. While respondents reported affirmative or neutral beliefs in the therapeutic benefits of CBD, the majority agreed more research was needed before they would feel comfortable recommending CBD for patient use. Lack of robust clinical data and self-identified deficits in knowledge were the most commonly cited concerns regarding CBD. Performance on knowledge questions demonstrated opportunities for additional education regarding the side effects, drug interactions, and legal product types of CBD. The majority of respondents expressed intentions to pursue additional education or training on CBD. Although not yet prevalent, future incorporation of cannabinoid medicines into pharmacy school coursework may be merited, as well as future research examining the impact of targeted CBD educational interventions.

**Timetable**

Jun. 2020	<ul style="list-style-type: none"> <li>• Manuscript submission to JAPhA Community-Based Pharmacy Residency Issue</li> </ul>
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**Evaluation Strategy**

Research project progress will be evaluated by peer pharmacy residents, pharmacy fellows, and residency research mentors and advisors on a biweekly basis. PGY-1 Community-Based Pharmacy Residents of programs partnered with Purdue University participate in a structured Research Project Development Program created and led by **Dr. Margie Snyder, PharmD, MPH, FCCP**. Dr. Snyder is an Associate Professor at the Purdue University College of Pharmacy and Co-Director of Community Pharmacy Programs, a role in which she founded and directs the Medication Safety Research Network of Indiana (Rx-SafeNet), a statewide practice-based research network of approximately 140 community pharmacies. Dr. Snyder has published over 35 peer-reviewed journal articles and mentored over 40 residents and fellows on research, many of which have received grant funding and/or publications in peer-reviewed journals. Dr. Snyder’s total extramural funding support to date equals approximately \$2.5 million as Principal Investigator and exceeds \$1 million as Co-Investigator. Dr. Snyder serves as a temporary reviewer for the NIH HSOD and AHRQ HCRT study sections. She has been named an outstanding/top reviewer for several major pharmacy journals including the

*Journal of the American Pharmacists Association, Pharmacotherapy, and Research in Social and Administrative Pharmacy.*

The Research Project Development Program is also co-facilitated by Dr. Snyder's research fellow, **Dr. Omolola "Lola" Adeoye-Olatunde, PharmD**. Dr. Adeoye-Olatunde successfully completed the Program as the PGY-1 Community Pharmacy Resident for Kroger/Purdue University in 2017 prior to becoming Dr. Snyder's research fellow. As a PGY-1 Resident, Dr. Adeoye successfully published her residency research in the *Journal of American Pharmacists Association*. Dr. Adeoye has positioned herself as a rising scholar in community pharmacy health services research with accolades such as a 2018 AcademyHealth Diversity Scholar recipient, 2018 American College of Clinical Pharmacy travel award recipient, and 2018 Consortium for Research in Administrative Pharmacy award recipient.

**Dr. Monica Miller, PharmD, MSc** is serving as primary research mentor and Principal Investigator on this project. Dr. Miller is an Associate Clinical Professor at the Purdue University College of Pharmacy and Co-Director of the Purdue University Global Health Residency. She has worked as an internal medicine clinical specialist with Eskenazi Health for the last 10 years and is also an integral member of Purdue's global health program. She has over 25 publications, has been the lead editor on two books, and has mentored approximately 20 pharmacy residents, several of whom secured grant funding and published in peer review journals. Dr. Miller's total grant funding support to date equals approximately \$950,000. She serves as a reviewer for several major pharmacy journals including the *Journal of the American Pharmacists Association, Pharmacotherapy, and Research in Social and Administrative Pharmacy.*

**Dr. Stephanie Arnett, PharmD, CDE** is serving as research site supervisor with Walgreen Co. and Co-Investigator on this project. Dr. Arnett is the Residency Program Director for the Walgreens/Purdue PGY-1 program where she has directed and mentored over 7 residents. She has worked in community pharmacy practice for over 17 years, 12 years as a pharmacist. Currently focusing in Specialty Pharmacy in the community setting, she is an Adjunct Clinical Assistant Professor of Pharmacy Practice and Regional Faculty Coordinator for Purdue University College of Pharmacy. Both the 2017-2018 and 2018-2019 residents of the Walgreens/Purdue program successfully published their research in the *Journal of American Pharmacists Association* under the mentorship of Dr. Arnett.

Areas of evaluation will include IRB protocol compliance via protocol checklist, manuscript draft review, resolution steps, and identification of professional presentation opportunities including poster presentations.

### **Budget**

<b>Category</b>	<b>Item</b>	<b>Budget</b>
Participant Incentives	\$10 gift card x 100 gift cards (raffled)	\$1000

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## **Appendix A: Survey Instrument**

### Community Pharmacist Preceptors and Their Knowledge, Experience, and Perceived Intent to Recommend Cannabidiol Products for Patient Use

#### Investigators

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#### Description

The primary purpose of this research project is to characterize community pharmacist preceptors' clinical and legislative knowledge on cannabidiol (CBD) products, CBD product experience, and perceived intent to recommend CBD products for patient use. The secondary purpose of this research project is to identify desired CBD resources for pharmacists. Eligible study participants include all pharmacists 18 years of age or older who read English, maintain an active pharmacist license, currently practice in the community pharmacy setting, and actively precept for an accredited college of pharmacy in the United States.

After stating you would like to participate in the survey, you will be directed to the secure online Qualtrics® survey. Completing the survey should take no more than 10-15 minutes.

#### Cost and Payments

There is no cost to participate in this research. After completing the survey, study participants will have the option to be directed to a voluntary web-based gift card raffle. There are 100 available Starbucks gift cards valued at \$10 each, limit one per participant. Depending on survey participation, the chance of winning a gift card is approximately 1 in 10. Raffle winners will be selected at random using Microsoft Excel®, notified via their preferred email by May 2020, and asked via this email for an address where the gift card can be mailed. The gift card will be mailed no later than the end of June 2020. Participant information will be stored on a secure hard drive. This data will be destroyed after no more than 5 years and will be accessed only by the principal investigator and co-investigators for the purpose of notifying raffle winners.

#### Risks and Benefits

Risk to study participants is minimal and no greater than the participant would encounter in everyday activities. Participants may enjoy being surveyed and knowing that their survey responses could facilitate the creation of additional educational materials on CBD. The study may also impact opportunities for colleges of pharmacy to provide preceptor education in their program development, thus benefiting the preceptors involved in the study.

### Confidentiality

No identifying information will be recorded or transmitted to researchers and nothing will link participants to their surveys. Since the collected survey data will be de-identified and no code key will be used, participants will not be able to withdraw data from the study after the electronic survey is completed. Data will be stored on a secure hard drive, and this data will be destroyed after no more than 5 years. Data will be accessed by the principal investigator and co-investigators for data analysis and interpretation of results. The project's research records may be reviewed by the study sponsor, US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight.

### Right to Withdraw

Your participation in this study is voluntary which means you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. If you have questions, comments, or concerns about this research project, please contact Molly Nichols, PharmD at [magnev@purdue.edu](mailto:magnev@purdue.edu). To report anonymously via Purdue's Hotline, see [www.purdue.edu/hotline](http://www.purdue.edu/hotline).

### IRB Approval

This study has been reviewed by Purdue University's Institutional Review Board (IRB). If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email ([irb@purdue.edu](mailto:irb@purdue.edu)), or write to:

Human Research Protection Program - Purdue University  
Ernest C. Young Hall, Room 1032  
155 S. Grant St.  
West Lafayette, IN 47907-2114

### Statement of Consent

I have read and understand the above information. By completing the survey I consent to participate in the study.

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### Survey Instrument

Are you a pharmacist 18 years of age or older who reads English, maintains an active pharmacist license, currently practices in a **community** pharmacy setting, and actively **precepts** for an accredited college of pharmacy?

- a. Yes
- b. No

### **Section 1: Demographics**

The following questions are designed to gather information about preceptor demographics. Please answer the questions truthfully and to the best of your ability.

1. What is your age?
  - a. [numeric sliding scale]
  
2. What is the highest level of education you have attained?
  - a. Bachelor of Pharmacy (BS)
  - b. Doctor of Pharmacy (PharmD)
  - c. Postgraduate education (Residency, Fellowship, PhD, etc.)
  - d. Other [free text box]
  
3. What is your primary US state of practice?
  - a. [drop-down list of states, alphabetical]
  
4. In what type of pharmacy setting is your current practice site?
  - a. Cannabis dispensary
  - b. Chain non-specialty (CVS, Walgreens, etc.)
  - c. Grocery store
  - d. Hospital outpatient
  - e. Independent
  - f. Mass merchandiser (Costco, Walmart, etc.)
  - g. Specialty pharmacy
  - h. Other [free text box]
  
5. What are the total years of experience you have working as a community pharmacist (with any employer)?
  - a. [numeric sliding scale]
  
6. With which college of pharmacy do you precept students? (If more than one, list the college from which you received this survey)
  - a. [free text box]

## **Section 2: CBD Product Experience**

The following questions are designed to identify preceptor experiences with CBD products. Please answer the questions truthfully and to the best of your ability.

7. What resources have you utilized to educate yourself on cannabidiol (CBD)?  
Select all that apply.
  - a. Accredited organization certification
  - b. Conferences
  - c. Continuing education (CE)
  - d. Informal personal research (internet sites, discussion with colleague, etc.)
  - e. No formal or informal education or training on CBD
  - f. On-the-job training
  - g. Other [free text box]
  - h. Pharmacy school classes
  - i. Webinars

8. How frequently do the following scenarios occur in your pharmacy?\*
- a. You are **asked** about **therapeutic uses** of CBD products.
    - i. Likert scale (Never, Less than once a month, Once a month or more, Once a week or more, Once a day or more)
  - b. You are **asked** about **adverse effects** of CBD products.
    - i. Likert scale (Never, Less than once a month, Once a month or more, Once a week or more, Once a day or more)
  - c. You are **asked** about **drug interactions** with CBD products.
    - i. Likert scale (Never, Less than once a month, Once a month or more, Once a week or more, Once a day or more)
  - d. You are **asked** to **recommend** a specific CBD product.
    - i. Likert scale (Never, Less than once a month, Once a month or more, Once a week or more, Once a day or more)
  - e. You **actually recommend** a specific CBD product for patient use.
    - i. Likert scale (Never, Less than once a month, Once a month or more, Once a week or more, Once a day or more)
9. Place the following in order of which group you most commonly have discussions or interactions with regarding CBD, where 1 = most common and 5 = least common.
1. Patients
  2. Pharmacy colleagues
  3. Prescribers
  4. Other healthcare professionals [free text box]
  5. Other [free text box]
10. Does your pharmacy sell any prescription or non-prescription CBD products?
- a. Yes
  - b. No
  - c. I don't know
- 10b. [Contingent on "Yes" response to item 10] Which CBD product(s) does your pharmacy sell? Select all that apply.
- a. Inhalation (inhalers, vape pens)
  - b. Oral (capsules or tablets)
  - c. Oral (edible food products or beverages)
  - d. Oral (oils or tinctures)
  - e. Prescription oral (Epidiolex®)
  - f. Topical (creams, lotions)
  - g. Topical (patches)
  - h. Other [free text box]

i. I don't know

11. Have you ever **personally** used a CBD product?
- a. Yes
  - b. No
  - c. I don't know
  - d. Prefer not to answer

11b. [Contingent on "Yes" response to item 11] Which CBD product(s) have you **personally** used? Select all that apply.

- a. Inhalation (inhalers, vape pens)
- b. Oral (capsules or tablets)
- c. Oral (edible food products or beverages)
- d. Oral (oils or tinctures)
- e. Prescription oral (Epidiolex®)
- e. Topical (creams, lotions)
- f. Topical (patches)
- f. Other [free text box]
- g. I don't know
- h. Prefer not to answer

### **Section 3: CBD Clinical and Legislative Knowledge**

The following questions are designed to assess preceptor clinical and regulatory/legislative knowledge of CBD. Please do not look up information or answers. Answer each question to the best of your ability. All responses are anonymous and will be presented in aggregate form. An answer key is available for your reference at the end of the survey.

12. CBD derived from *Cannabis sativa* containing  $\leq 0.3\%$  THC (also known as "hemp"), is **not** a controlled substance.
- a. **True**
  - b. False
  - c. I don't know
13. Food products and dietary supplements are legally allowed to contain CBD derived from any source.
- a. True
  - b. **False**
  - c. I don't know
14. If your state has legalized CBD, this supersedes federal law.
- a. True
  - b. **False**
  - c. I don't know
15. CBD on its own produces euphoric effects.

- a. True
- b. False**
- c. I don't know

16. Which are the **most prominent** CYP-mediated drug interactions with CBD?

Select all that apply.

- a. CYP 2C9
- b. CYP 2C19**
- c. CYP 2D6
- d. CYP 3A4**
- e. I don't know

17. Which are potential side effects of CBD? Select all that apply.

- a. Appetite suppression**
- b. Diarrhea**
- c. Euphoria
- d. Increased suicidal ideation**
- e. Kidney injury
- f. Liver injury**
- g. Somnolence and sedation**
- h. I don't know

#### **Section 4: Theory of Planned Behavior Constructs**

The following questions are designed to identify factors that may influence preceptors' perceived intent to recommend CBD products. Please answer the questions truthfully and to the best of your ability.

Likert Scale:

- 1 – Strongly Disagree
- 2 – Disagree
- 3 – Neutral
- 4 – Agree
- 5 – Strongly agree

*Construct: Attitude Towards Behavior*

18. I believe CBD provides therapeutic benefit in many disease states.\*

- a. Likert scale

19. I am comfortable counseling patients on CBD products.\*

- a. Likert scale

20. I am comfortable recommending a specific CBD product for patient use.\*

- a. Likert scale

21. In general, more research is needed before I would feel comfortable recommending the use of CBD products in most disease states.  
a. Likert scale

*Construct: Subjective Norms*

22. I believe **patients** in my community would be disappointed if I did not recommend CBD products for their personal use.\*\*  
a. Likert scale
23. I believe **prescribers** in my community would approve of me recommending CBD products for patient use.\*\*  
a. Likert scale
24. I know other **pharmacy colleagues** who recommend CBD products for patient use.\*\*  
a. Likert scale

*Construct: Perceived Behavioral Control*

25. I have the necessary knowledge to counsel patients on CBD products.  
a. Likert scale
26. I have the necessary knowledge to recommend a specific CBD product for patient use.  
a. Likert scale
27. I have reliable resources available in my pharmacy on CBD products, including but not limited to their availability, therapeutic uses, and/or adverse effects.  
a. Likert scale
28. I feel pressure from **patients** to recommend CBD products.  
a. Likert scale
29. I feel pressure from **prescribers** to recommend CBD products.  
a. Likert scale

*Construct: Intent*

30. I plan to pursue additional education and training on CBD products.  
a. Likert scale
31. I intend to counsel more patients on CBD products.  
a. Likert scale
32. I intend to recommend more CBD products for patient use.

- a. Likert scale

**Section 5: Additional Information**

33. How confident are you in your knowledge of your state's laws surrounding the sale of CBD products?

- a. Likert scale
- b. [free response] for additional comments

34. For which of the following disease states have or would you recommend CBD products for patient use? Select all that apply.\*

- a. Alzheimer's
- b. Anxiety
- c. Arthritis
- d. Cancer
- e. Depression
- f. Diabetes
- g. Inflammation
- h. Insomnia
- i. Multiple sclerosis
- j. Nausea or vomiting
- k. Pain
- l. Parkinson's
- m. Schizophrenia
- n. Seizure disorders
- o. Substance use disorder
- p. Other [free text box]
- q. I do not recommend CBD products for patient use

35. What worries or concerns do you have about recommending or selling CBD products in your pharmacy?

- a. [free response]

36. What resource(s) do you use for information on CBD? What additional resource(s) or training(s) on CBD would be beneficial for community pharmacists to have prior to recommending or dispensing CBD products?

- a. [free response]

\*Questions adapted from Kogan et al 2019

\*\*Questions adapted from Adeoye et al 2018

## Appendix B: Tables

**Table 1**

Respondent demographics (N = 265)

Characteristic	Results
Age in years, median (range)	39 (25-69)
Total community pharmacy experience in years, median (range)	13 (1-43)
Highest level of education attained, n (%)	-
Doctor of Pharmacy (PharmD)	170 (64.1%)
Bachelor of Pharmacy (BS)	78 (29.4%)
Postgraduate education (Residency, Fellowship, PhD, etc.)	18 (6.8%)
Other <sup>a</sup>	1 (0.3%)
Current pharmacy practice setting, n (%)	-
Chain non-specialty (CVS, Walgreens, etc.)	87 (32.8%)
Independent	83 (31.3%)
Grocery store	46 (17.4%)
Hospital outpatient	16 (6.0%)
Other <sup>b</sup>	14 (5.3%)
Mass merchandiser (Costco, Walmart, etc.)	10 (3.8%)
Specialty pharmacy	9 (3.4%)
Primary US state of practice, <sup>c</sup> n (%)	-
South Region	102 (38.5%)
Midwest Region	90 (33.9%)
Northeast Region	49 (18.5%)
West Region	24 (9.1%)

<sup>a</sup> Other: MBA

<sup>b</sup> Other (n, %): Clinic outpatient (6, 2.3%), Federally Qualified Health Center outpatient (2, 0.75%), Long term care (2, 0.75%), Cannabis dispensary (1, 0.37%), Managed care (1, 0.37%), Pharmacy Benefit Manager (1, 0.37%), Other non-specified (1, 0.37%)

<sup>c</sup> South Region: AL, AR, DC, DE, GA, FL, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV; Midwest Region: IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI; Northeast Region: CT, MA, ME, NH, NJ, NY, PA, RI, VT; West Region: AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY

**Table 2**

Experience-item survey responses

CBD Experience	N	Preceptors, n (%)
Previous education on CBD	247	-
Mixed education and personal research <sup>a</sup>		175 (70.9%)
Continuing education	175	148 (84.6%)
Personal research <sup>b</sup>		105 (60.0%)
On-the-job training		59 (33.7%)
Webinars		51 (29.1%)
Conferences		41 (23.4%)
Accredited organization certification		24 (13.7%)
Other <sup>c</sup>		7 (4.0%)
Pharmacy school classes		5 (2.9%)
Personal research only	247	34 (13.8%)

No education or personal research		38 (15.4%)
Prescription or non-prescription CBD sales in the pharmacy	247	-
Independent pharmacy practice setting	75	-
Yes		61 (81.3%)
No		14 (18.7%)
All other community pharmacy practice settings	171	-
Yes		58 (33.9%)
No		112 (65.5%)
I don't know		1 (0.6%)

<sup>a</sup> Responses not mutually exclusive, sum total over 100%

<sup>b</sup> Personal research: Discussion with colleague, internet search, or student rotation project

<sup>c</sup> Other (n, %): Information from wholesalers, manufacturers, vendors, or company customer service (5, 2.9%), national speaker (1, 0.6%), pharmacy magazines (1, 0.6%)

**Table 3**

Experience-item: How frequently do the following scenarios occur in your pharmacy?<sup>a</sup>  
(N = 247)

Survey Item	Preceptors, n (%)				
	Never	Less than once per month	Once per month or more	Once per week or more	Once per day or more
You are asked about <b>therapeutic uses</b> of CBD products.	27 (10.9%)	71 (28.7%)	80 (32.4%)	45 (18.2%)	24 (9.7%)
You are asked about <b>adverse effects</b> of CBD products.	62 (25.1%)	69 (27.9%)	65 (26.3%)	37 (15.0%)	14 (5.7%)
You are asked about <b>drug interactions</b> with CBD products.	58 (23.5%)	68 (27.5%)	67 (27.1%)	40 (16.2%)	14 (5.7%)
You are asked to <b>recommend</b> a specific CBD product.	84 (34.0%)	52 (21.1%)	49 (19.8%)	44 (17.8%)	18 (7.3%)
You <b>actually recommend</b> a specific CBD product.	144 (58.3%)	30 (12.2%)	24 (9.7%)	34 (13.8%)	15 (6.1%)

<sup>a</sup> Adapted with permission from Kogan et al (2019)<sup>21</sup>

**Table 4**

Knowledge-item survey responses

Survey Item	N	Preceptors, n (%)		
		Correct	Incorrect	"I don't know"
1. CBD derived from Cannabis sativa containing ≤0.3% THC (also known as "hemp") is <b>not</b> a controlled substance. <i>Answer = true</i>	239	200 (83.7%)	18 (7.5%)	21 (8.8%)
2. Food products and dietary supplements are legally allowed to contain CBD derived from any source. <i>Answer = false</i>		130 (54.4%)	50 (20.9%)	59 (24.7%)

3. If your state has legalized CBD, this supersedes federal law. <i>Answer = false</i>		174 (72.8%)	42 (17.6%)	23 (9.6%)
4. CBD on its own produces euphoric effects. <i>Answer = false</i>	238	205 (86.1%)	15 (6.3%)	18 (7.6%)
5. Which are the <b>most prominent</b> CYP-mediated drug interactions with CBD? <i>Answer = CYP 2C19 and CYP 3A4</i>		11 (4.6%)	107 (45.0%)	120 (50.4%)
6. Which are potential side effects of CBD? <i>Answer = appetite suppression, diarrhea, increased suicidal ideation, liver injury, and somnolence and sedation</i>		-	173 (72.7%)	65 (27.3%)

**Table 5**  
Theory of Planned Behavior survey responses

Survey Item	N	Mean (SD)	Preceptors, n (%)				
			Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
<b>Construct: Attitude Towards Behavior</b>							
1. I believe CBD provides therapeutic benefit in many disease states. <sup>a</sup>	238	3.41 (0.98)	9 (3.8%)	27 (11.3%)	93 (38.9%)	78 (32.6%)	32 (13.4%)
2. I am comfortable counseling patients on CBD products. <sup>a</sup>		2.71 (1.24)	46 (19.3%)	71 (29.7%)	53 (22.2%)	47 (19.7%)	22 (9.2%)
3. I am comfortable recommending a specific CBD product for patient use. <sup>a</sup>		2.48 (1.26)	66 (27.6%)	68 (28.5%)	48 (20.1%)	39 (16.3%)	18 (7.5%)
4. In general, more research is needed before I would feel comfortable recommending the use of CBD products in most disease states.		3.96 (1.04)	7 (2.9%)	19 (7.4%)	35 (14.6%)	92 (38.5%)	86 (36.0%)
<b>Construct: Subjective Norms</b>							
5. I believe <b>patients</b> in my community would be disappointed if I did not recommend CBD products for their personal use. <sup>b</sup>		2.95 (1.06)	21 (8.8%)	63 (26.4%)	79 (33.1%)	60 (25.1%)	16 (6.7%)
6. I believe <b>prescribers</b> in my community would		3.02 (0.96)	16 (6.7%)	45 (18.8%)	111 (46.4%)	52 (21.8%)	15 (6.3%)

approve of me recommending CBD products for patient use. <sup>b</sup>							
7. I know other <b>pharmacy colleagues</b> who recommend CBD products for patient use. <sup>b</sup>		3.22 (1.08)	11 (4.6%)	65 (27.2%)	46 (19.3%)	95 (39.8%)	22 (9.2%)
<b>Construct: Perceived Behavioral Control</b>							
8. I have the necessary knowledge to counsel patients on CBD products.	237	2.44 (1.17)	57 (24.1%)	83 (35.0%)	42 (17.7%)	45 (19.0%)	10 (4.2%)
9. I have the necessary knowledge to recommend a specific CBD product for patient use.		2.41 (1.21)	64 (27.0%)	82 (34.6%)	34 (14.4%)	45 (19.0%)	12 (5.1%)
10. I have reliable resources available in my pharmacy on CBD products, including but not limited to their availability, therapeutic uses, and/or adverse effects.		2.52 (1.22)	55 (23.2%)	82 (34.6%)	35 (14.8%)	51 (21.5%)	14 (5.9%)
11. I feel pressure from <b>patients</b> to recommend CBD products.		2.39 (1.14)	57 (24.1%)	91 (38.4%)	38 (16.0%)	42 (17.7%)	9 (3.8%)
12. I feel pressure from <b>prescribers</b> to recommend CBD products.		1.91 (0.89)	86 (36.3%)	103 (43.5%)	35 (14.8%)	10 (4.2%)	3 (1.3%)
<b>Construct: Intent</b>							
13. I plan to pursue additional education and training on CBD products.		3.84 (0.86)	5 (2.1%)	13 (5.5%)	41 (17.3%)	133 (56.1%)	45 (19.0%)
14. I intend to counsel more		3.30 (0.97)	13 (5.5%)	25 (10.6%)	99 (41.8%)	77 (32.5%)	23 (9.7%)

patients on CBD products.							
15. I intend to recommend more CBD products for patient use.		2.94 (1.10)	32 (13.5%)	38 (16.0%)	95 (40.1%)	56 (23.6%)	16 (6.8%)

<sup>a</sup> Adapted with permission from Kogan et al (2019)<sup>21</sup>

<sup>b</sup> Adapted with permission from Adeoye et al (2018)<sup>29</sup>