The State of Medical Use of Cannabidiol in Older Adults in 2023
GSA Policy Podcast from The Gerontological Society of America

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Patricia D'Antonio:

Welcome to the GSA Policy Profile podcast. GSA Policy Profiles provide insights into current aging related policy issues from those at the forefront working to develop evidence-based policy. We are grateful to Jazz Pharmaceuticals, formerly Greenwich Pharmaceuticals, for their support of the 2021 GSA publication, *Medical Use of Cannabidiol in Older Adults*, which was based on a convening of experts in pharmacy, clinical medicine, research, law, and policy. Since 2021, communities of interest have been active in conducting research, producing clinical education, raising awareness of risks and benefits of CBD, and advocating for appropriate federal and state laws. My name is Patricia D'Antonio, and I am the Vice President of Policy and Professional Affairs at GSA. The use of cannabis among older adults is increasing in the United States. While cannabis has been suggested to help alleviate chronic symptoms experienced by older adults, its potential adverse effects may lead to unintended consequences, including increased acute healthcare utilization related to its use.

I am here today to discuss with panelists what has happened in the environment since 2021 in this podcast titled, *The State of Medical Use of Cannabidiol in Older Adults in 2023*. Joining me today are two individuals who have been engaged on issues associated with cannabidiol for many years. Libby Baney is a partner at Faegre Drinker and works primarily on policies and issues confronting health stakeholders. She also serves as the Secretariat of the Collaborative for Cannabinoid Science and Safety, whose goal is to foster dialogue and cooperation among a diverse group of stakeholders interested in encouraging scientifically based research into the therapeutic potential of cannabinoids and ensuring the quality and safety of cannabinoids and cannabinoid containing products available for consumer use. And joining Libby is Carmen Witsken, who is an Executive Fellow in Association Leadership and Management with the American Society of Consultant Pharmacists (ASCP). Her responsibilities at ASCP include providing critical insights to the society's government and regulatory affairs portfolios, serving as the primary student liaison and APPE preceptor, and engaging in strategic partnerships through committees and coalitions. Welcome and thank you for joining us today on our podcast. And I thought, Carmen, I could start with you. Would you explain to us what cannabidiol (CBD) is and how it compares to those other terms that our audience may use, such as cannabis, marijuana, medical marijuana, hemp? Can you explain what cannabidiol (CBD) is?

Carmen Witsken:

Cannabidiol (CBD) is one of the hundreds of cannabinoids in the cannabis plant. THC is an example of another cannabinoid in the cannabis plant. CBD or cannabidiol is within the cannabis plant, thus the plant derived form. There are plant derived cannabinoids, naturally occurring exogeneous cannabinoids, and synthetic. CBD is plant derived as it is one of the many compounds in the cannabis plant.

Patricia D'Antonio:

Thanks. How about when I hear the term marijuana?

Carmen Witsken:

Marijuana is a plant that has more than 0.3% THC within the plant. This is a federally controlled substance. This is considered schedule I by the FDA. The THC concentration is what differentiates marijuana from cannabis. Hemp is a cannabis plant that has less than that 0.3% THC.

Patricia D'Antonio:

Most recently we have heard of the term medical marijuana. Is that the same or is it different?

Carmen Witsken:

It is the same marijuana; however, it is used for different purposes. Medical marijuana and recreational marijuana are the same product. However, the purpose of medical marijuana is to treat disease or alleviate symptoms of disease. Medical marijuana is legal in some states and not in others. It is important to know which state you are in and if it has been legalized there.

Patricia D'Antonio:

Right. If I understand correctly, there is no FDA approved use for medical marijuana.

Carmen Witsken:

Yes. Just state approved use.

Patricia D'Antonio:

CBD is found in the cannabis plant. How would people find CBD in products? How would our listeners recognize CBD compared to medical marijuana?

Carmen Witsken:

Our patients usually see CBD in stores, often in oils or tinctures, and advertised for topical pain relief. We might also see CBD in a gummy form. I've seen commercials that advertise CBD for sleep or general mood boosts. It is becoming more commercialized. We do not just see them online anymore. We see them mixed in with all your other medications in the store aisles.

Patricia D'Antonio:

Thanks Carmen. Libby, could you talk about the legal status of CBD and cannabinoids in foods and supplements?

Libby Baney:

I'm listening to this conversation, thinking about your audience walking through a store, finding CBD gummies, and not realizing that is an illegally marketed product. The FDA has acknowledged that there is certainly consumer interest, evidenced by what Carmen just said. Products are showing up both online and offline with CBD in them, but the FDA has maintained that products containing CBD may not be sold in food or dietary supplement formulations. Topical creams or getting a massage with CBD oil is permitted. However, putting CBD in food and in dietary supplement form, to help with sleep or stress, has not been permitted by the U.S. FDA. There are details I could go into, but the short version is that current law precludes the use of CBD in a food or dietary supplement if it was previously approved for use in a prescription drug.

Since CBD has been approved for use as a prescription drug the FDA has the authority, but has not used it, to waive what they call the IND bar to allow that otherwise prescription drug to be used in other formulations. The FDA has not done that in this case, and therefore, the only legal use of CBD is in a prescription drug formulation but not in a food or dietary supplement. This is because this CBD article

has been subject to substantial clinical evidence and gone through clinical trials. It is a FDA approved drug and therefore, the FDA has not authorized CBD to be marketed in foods or supplements.

Patricia D'Antonio:

Thank you. Could you comment further on the recent FDA determination that a new regulatory pathway is needed for CBD? We understand there is a need to balance an individual's desire for access to CBD products, within regulatory oversight, while managing risk. We want to ensure any product on the market is safe for people, particularly (from our perspective) for older adults. Can you give us an overview of what happened and what might happen next?

Libby Baney:

Thanks for that question. Since this is an update from 2021, Patricia, it is important to show that there has been a shift since 2021 when GSA came out with the paper. There was an open question as to what the FDA was going to do. Would they use the existing regulatory framework that they have in law as a supplement, food, or drug to allow more CBD products on the market? And on January 27, 2023, now two years after that paper, the U.S. FDA announced that a new regulatory pathway for CBD. The pathway is needed to balance individuals' desires for access to CBD products with the regulatory oversight needed to manage risks. The important words in the FDA's statement are that there is a new regulatory pathway. And following that sentence from the FDA, they also said they plan to work with Congress to develop this new regulatory pathway, which could be based on an existing regulatory pathway.

As a lawyer, I like to think we use precedence as a guide. The FDA did not say they are going to put CBD into the existing framework for food and dietary supplements. Instead, it stated that we need a new regulatory pathway. Carmen, I know that as a member of the Collaborative for Cannabinoid Science and Safety, the Collaborative for which I serve as Secretariat, ASCP has been a long-standing member in response to actions. I know you and others helped us guide a statement and response. I wonder if you want to share with the listeners more about that.

Carmen Witsken:

As part of the Coalition, we are one of many members that have a lot at stake here. We represent consultant pharmacists or senior care pharmacists who work with older adults in all settings. More research is important for our pharmacists to help their patients. When the FDA said that they want to create a new pathway, it just created more confusion for our members. I received many emails asking, "what does this mean?" And, "do I need to be watching the news and making sure that we are not going to be held liable at our facility for the medical marijuana that we do have in our facility?" I think it created a lot of confusion. We put together a white paper with specific requests, and from our perspective, the biggest ask is the FDA needs to change the scheduling so that there can be more research done. If we have more research, then we can show the safety and efficacy that we need. However, the creation of a new pathway caused confusion.

Patricia D'Antonio:

Thanks. Libby, I was wondering if you could follow up a little more on the issues of labeling and some of the other issues that were included in the ask from the Collaborative.

Libby Baney:

I appreciate you raising that. We are concerned. Just as the FDA has done, the Collaborative has expressed concern regarding the existing frameworks being sufficient. The agency calls for tools to manage risk, including clearer labels. And we can talk about what is in the product. What is on the label needs to be in the product. Similarly, the FDA has signaled concern of whether the existing regulatory pathway is sufficient to address this product category. And I think that is important. The FDA's statement was specific in addressing if these pathways are sufficient for CBD. We know that CBD has clinical efficacy through the drug approval process, but it also has risks, which means that toxicity impacts were identified in the clinical trials. The FDA's statement addresses the need for clearly labeling if there is going to be CBD in a product. The prevention of contaminants was also addressed in the FDA's statement. In addition, concentration limits, which would prevent patients from accidental overdose of a supplement product that has potentially too high or too potent a dose of CBD. This comes out of the clinical evidence that the FDA used for the drug approval, recognizing at certain levels there can be toxic effects of even commercially available CBD products in a dietary supplement formulation, which is why concentration limits is another issue of focus of the Collaborative.

Patricia D'Antonio:

Fantastic. Thank you for that. Carmen, I was wondering if you could comment on the following. There was a recent article published in *Geriatrics*, which showed that the overall rate of emergency department visits in the state of California increased from 20.7 per 100,000 visits in 2005 to 395 per 100,000 emergency department visits in 2019. That represents over an 1800% increase, a relative increase. Poison centers have seen an increase across the country for people of all ages since 2014. Can you talk about some of the adverse effects of CBD and the impact on our health system?

Carmen Witsken:

That article specifically mentions patients 65 years and up. It is important to know that that growth is in a select number of patients while older adults are experiencing greater impact. A lot of the symptoms that cause people to call poison control centers or go to the emergency department include insomnia, diarrhea, rash, vomiting, and infections. These patient-reported symptoms have caused an increase in calls to the poison control center. We have also seen elevated liver enzymes, which cause poor results for patients, leading to emergency department visits. When older adults are on medications that affect their liver or they already have liver issues, there can be harmful interaction between CBD and their medications. Older adults typically take more medications, as well as vitamins and supplements, which is why we might be seeing this increase in numbers.

Overall, there are several inert ingredients in CBD products. Since they are over the counter, older adults may not consider them harmful, particularly if they're labeled as natural products. But they can certainly have negative effects depending on medical history and other medications being taken. This is a growing concern for all of us, but especially for older adults. It is very important to talk to your doctors and pharmacists about all the medications you are using, including over the counter, because there are adverse effects that are concerning for patients**.**

Patricia D'Antonio:

Thank you. I see that tie back again to what Libby stressed about the importance of recognizing concentrations and labeling that the FDA discussed. We've seen several organizations such as the Alzheimer's Association and the American Heart Association issue statements concerning safety concerns about CBD products. Libby, I was wondering if you could address some of the safety concerns on the market today.

Libby Baney:

As mentioned, there have only been four cannabinoid-based prescription drugs that have been approved by the FDA. One is a plant derived CBD and three are synthetic THC drug products. These are available with a prescription from a licensed healthcare provider. These have demonstrated safety and efficacy, and they followed the extensive FDA drug approval process. Since they require a prescription, individuals who take them can discuss the effects with their doctor and healthcare professionals. You get the wraparound benefit of healthcare when you take an FDA approved drug. Unfortunately, as we've been hearing, there are many products that include any form of cannabinoids. We are focused on CBD for this conversation. But other cannabinoids are also in products that are marketed and distributed outside of the prescription drug legal pathway. Those products might contain things that are different than what their label says.

A study of CBD containing products conducted by the FDA found that many of these products marketed for consumers contain different levels of CBD than indicated. The FDA's ruling is that what is on the label needs to be what is in the bottle. Moreover, nearly half of the products that FDA tested contained THC, even though THC was not listed at all. I love my older, American parents, but I do not want my mother taking a CBD gummy and I walk in when she's high. What the FDA has been identifying is an emergence of this market without the regulatory framework to support it. They really have not been able to ensure that what is in the product is on the label.

The FDA has issued many warning letters to companies marketing CBD products on these same issues. The FDA has (with limited resources) been trying to use their agency authority to go after people making claims about the ability of CBD to prevent things like Covid or Alzheimer's Disease. You can see the Alzheimer's Association and others raising those concerns because marketing uses hype around CBD to claim any type of cure or treatment. The FDA and others have found that CBD products being marketed today contain varying levels of quality, dosing, and purity. The production of those products may come from environments that are contaminated, which could create other toxins or poisons in the products as well. And I'll leave it at that. It is a little bit like the "Wild West" right now, which speaks to the FDA's interest in creating a new regulatory framework for this type of cannabinoid product.

Patricia D'Antonio:

Carmen, were you going to add something?

Carmen Witsken:

Libby mentioned that there is THC hidden in some of these products, which is very concerning, especially for patients that have anxiety or paranoia. That would be harmful to them and could make their disease states much worse. I wanta to note that these products are not always safe. Do not

consider them safe. They could have detrimental effects, especially with THC hidden in some of these products.

Patricia D'Antonio:

Thank you. We really do have to know what we are using when we are purchasing these products off-label. And thinking about that, we also know that private insurance is being lobbied to include CBD products in their coverage. Libby, what's happening there? What advocacy strategies are you hearing of?

Libby Baney:

I'll differentiate what we've been talking about, which is prescription drug products versus over the counter medical or dietary supplement products. Those are not coverage issues. Let's talk about mandatory payment issues as some states move to legalize marijuana. We talked about marijuana, which has a higher THC concentration for recreation or medical use. Marijuana in a medical context is when doctors are writing prescriptions for marijuana for medical use. There have been several lobbying activities in some states to push for mandatory reimbursement for medical marijuana prescription. The theory is that if it is a prescription, it should be covered by insurance. Medical marijuana is not being reimbursed by Medicare or Medicaid (federal payers or state payers) or other private health insurances due to its schedule I status. There is some traction in trying to make mandatory reimbursement in workers' compensation programs - another mandatory payment system for prescription drugs. Providing reimbursement for medical marijuana without having clearly established safety and efficacy for medical treatments, puts patients at risk and creates an undue tax burden. Mandating payment for something that hasn't been clinically proven to be safe and effective for the intended use is a slippery slope. That would allow doctors to write scripts for pretty much anything and perhaps getting a political body to require mandatory payment for that "prescription." I use "prescription" in quotes because the prescription here is not for something that has been proven as safe and effective by the FDA but instead has been approved by a state for medical use, which are two very different things. We are seeing a trend in some states that workers' compensation programs are being encouraged, with six states expressly allowing mandatory reimbursement and other states are considering it. We could go down a rabbit hole talking about this, but I think it is important for your audience to think about the implications of state insurance mandates requiring payment for things that are not FDA approved.

Patricia D'Antonio:

As you mentioned at the top of the question, we could probably have a podcast dedicated completely to this topic. It is important to remember how we use our terms. We are talking about CBD when we are talking about medical marijuana use and recommendations from a healthcare provider. What does that imply and what's been approved and studied to prove efficacy and safety? There is a community of interest proposing regulating these types of CBD products to ensure that all people are safe. Could you talk a little bit more about the Collaborative's regulatory positions? We went into it a little bit but is there anything more that you want to add to that?

Libby Baney:

Thanks for asking about that. The Collaborative has been working for a couple years now in response to the regulatory changes in this environment and I'm pleased to have you all involved in this discussion to try to create consensus around cannabinoid science and safety. The Collaborative has come together to address the importance of reducing barriers to research and for rescheduling cannabinoid formulations

for medical research. It goes to what Carmen has been saying about schedule I versus other schedules. We need to be able to study the product and changing the scheduling would help with that. The Collaborative has spent time thinking about policies that would drive research and advance the development of cannabinoid-based medications that have been reviewed and approved by the FDA, while still maintaining the FDA's standard review and the high level of quality and efficacy that the agency has been known for.

The FDA stated the need for a new regulatory pathway. Questions that come up in response to that include, what does that new regulatory pathway look like? What are the elements of success? If the FDA is going to work with Congress on a potential new CBD pathway, the Collaborative has been thinking about establishing a science-based regulatory pathway consistent with FDA's "Call-to-Action." This pathway would include how those products should be marketed safely as dietary supplements or other cannabinoid-based products. This pathway must direct the FDA to establish a national standard for maximum daily serving limits and per package levels for CBD and the total amount of THC. This reflects the important issue of knowing what you are taking and ensuring that information is on the label. In addition, there needs to be guidance on whether there is a sufficient concentration or a minimum concentration limit in the market to ensure safety of over-the-counter product consumption. They need to know what they're taking and not be at high risk for toxicity or other adverse effects that have been proven in the literature. In addition, the Collaborative has supported the mandatory product listing for dietary supplement products, noting our interests in the Collaborative are really for requiring cannabinoid-based products to be listed with the FDA.

Patricia D'Antonio:

Thanks, Libby. And Carmen, I want to direct this final question to you before I ask us to wrap up. What should our audience communicate about cannabidiol with older people, friends, and family?

Carmen Witsken:

It is important to understand the patients' perspective as the first thing when talking with patients. A lot of times they're having uncontrolled symptoms and they feel like they want to try anything to try to relieve their symptoms. And when talking to them about the CBD products they are using, ask if they are having any side effects that are new, and discuss potential risk while linking potential side effects with the medications they are taking. Inform the patient that although it is over the counter it could have side effects and be potentially harmful. The CBD may help but we would prefer that these products are labeled correctly to ensure patient safety. They need to know their CBD has not been FDA approved. There are risks when taking this medication. Patients need to be able to weigh the risks and benefits for themselves and be informed on their decision.

It is important to understand the patients' perspective. Frequently, they are having uncontrolled symptoms and they want to try anything to try to relieve their symptoms. And when talking to them about the CBD products that they're using, ask if they are having any side effects that are new, and discuss potential risk while linking potential side effects with the medications they are taking. Inform the patient that although it is over the counter it could have side effects and be potentially harmful. The CBD may help but we would prefer that these products are labeled correctly to increase safety for our patients. They need to know their CBD has not been FDA approved. There are risks when taking this medication when there are already medications being taken that have been FDA approved and do work. Having the patient be able to weigh the risks and benefits for themselves and be informed on their decision is important.

Patricia D'Antonio:

Thank you. As we wrap up, Carmen, do you have any final thoughts that you'd like to remind our listeners of?

Carmen Witsken:

I think our listeners here are most likely going to be patients, providers, and caregivers of all backgrounds. But I what to encourage people to look up resources for the developments in CBD science and look for events from organizations that you are a part of. We can provide some, along with this posting, but it is important for providers to be aware of CBD and its uses. Pharmacists and providers do not want to discuss it when it is less known. Unfortunately, that doesn't help patients because patients want to learn about CBD. Patients want to find solutions to their symptoms and to their disease states. Seek out information where you can and ask your organizations to provide information so that you may provide resources toto your patients. At the end of the day, patients will make the decision, therefore they need all the information that is available to them. You are the person that can give that to them.

Patricia D'Antonio:

Great. And Libby?

Libby Baney:

In addition to what Carmen stated, I want to focus on the legal status of these products. As a lawyer, I'm a rule of law person, but the legal status is important for a reason. Currently, there is no determination of the concentration of products used for consumer purposes outside the prescription drug pathway. It is important for healthcare providers and regulated entities, like law and healthcare, to understand those risks and benefits that Carmen mentioned. Ask questions of patients such as, “Are you taking additional products as you always do? Are you buying them over the counter? Do you know about the potential risks of commercially available CBD products marketed with CBD and thinking about the adverse effects and possible drug or drug supplement interactions?”

I appreciate GSA's leadership in trying to educate the community on this because it is a complicated topic, but one that has a clear law and regulatory basis for the time being. We will see where Congress takes this work with the Agency, and if there is going to be a legal pathway for non-prescription products marketed with CBD. As of right now, it is buyer beware on the market.

Patricia D'Antonio:

I want to thank you both. This is an emerging field. This is something that we must be mindful of when we are working with our patients and when we are working with older people. I think a couple of the things that we advocate for and why we so appreciate being part of the Collaborative is that we all recognize the need for the evidence to inform the policy and the evidence to inform practice.

As a reminder, our 2021 publication is online at geron.org. We will include some of the publications that Libby and Carmen referenced in this podcast on our website as well. Thank you, Libby, and Carmen, for joining me on this GSA Policy Profile podcast. And thanks to Jazz Pharmaceuticals for your support. And again, thank you for listening to the program.

Announcer:

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