THE GERONTOLOGICAL SOCIETY OF AMERICA®

MEDICAL USE OF **CANNABIDIOL(CBD)** IN OLDER ADULTS:

A FOCUSED DISCUSSION ON SAFETY

SUMMARY OF PROCEEDINGS FROM
THE GERONTOLOGICAL SOCIETY OF AMERICA

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INTRODUCTION

As cannabidiol (CBD) products have become increasingly available, older adults are exploring their use for a wide variety of chronic diseases. Whereas cannabis used for medical purposes is sold through state-licensed dispensaries, CBD products may be sold, depending on the laws and regulations of a particular state, in dispensaries or through other retail stores, including online stores.

Despite a perception that these products are low risk, there are many evidentiary gaps in research on CBD and pending questions about the safety of CBD products.[1] What ingredients are contained in CBD products? What effects can be expected? Do CBD products interact with prescription or over-the-counter medications? What evidence supports their use for common chronic conditions such as pain, insomnia, loss of appetite, depression, anxiety, and weight loss? What is the role of health care providers in counseling patients on the use of products that may be perceived to be outside the realm of the clinician? These questions are consistent with recent concerns expressed by the U.S. Food and Drug Administration (FDA) regarding "unanswered questions about the science, safety, and quality of many of these products."[2]

These concerns become more pronounced when combined with the human aging process and how an individual's changing physiology may result in increased risk for side effects. To create clarity around use and safety of CBD for medical purposes in older adults (defined for the scope of this report as individuals aged 55 years and older), The Gerontological Society of America (GSA) convened a panel of experts in various relevant disciplines (pharmacy, clinical medicine and research, law and policy) and stakeholders in both the patient and professional arenas. This white paper summarizes presentations on pertinent topics and ideas for consideration developed by stakeholders.

Terminology

Terminology used to describe products containing CBD and more broadly, cannabis, is evolving and complex. In developing this summary of proceedings, GSA referenced the Common Terminology & Glossary of The Collaborative for CBD Science and Safety (CCSS).[3] CCSS is a multistakeholder group focused on advancing the evidence base for safe and high-quality CBD and CBD-containing products. Key terms are presented in Table 1.

Table 1. General Purpose Definitions Used by The Collaborative for CBD Science and Safety

Term	General Purpose Definition*
Cannabidiol/CBD	Cannabidiol is a nonpsychogenic cannabinoid derived from cannabis or synthesized.
Cannabinoids	Cannabinoids are molecules that can be classified as phytocannabinoids, endocannabinoids, or synthetic cannabinoids. • **Phytocannabinoids:** Over 100 naturally occurring chemicals found in the cannabis plant with a chemical structure related to endocannabinoids. Some of the most well-characterized so far include CBD and THC. • **Endocannabinoids:** Chemicals produced by the body that target cannabinoid receptors. • **Synthetic Cannabinoids:** Cannabinoids produced in the laboratory to structurally or functionally mimic the endocannabinoids or phytocannabinoids.
Cannabis	The generic term for all parts and derivatives of the plant *Cannabis sativa* L. Historically this included varieties sativa, indica, and ruderalis. Now, most varieties of cannabis are hybrids, needing a composition analysis to determine cannabinoid content. Legally, cannabis is subdivided into two terms: hemp and marijuana. With limited exceptions, cannabis (and its cannabinoid components) is a Schedule I controlled substance in the United States; this classification denotes a drug with a high potential for abuse and no currently accepted medical use.
Hemp	Hemp is a type of *Cannabis sativa* L. historically grown for seeds and fibrous materials found in stalks. In 2014, hemp was legally defined as a cannabis plant containing less than 0.3% of THC by dry weight. The 2018 Farm Bill expanded the definition of hemp to include extracts, derivatives, and cannabinoids with less than 0.3% of THC by dry weight.
Marijuana	Marijuana is the name commonly applied to the dried resinous flower buds and leaves of the *Cannabis sativa* L. plant (or extracts or concentrates thereof) with a THC content of more than 0.3% (and often 15% to more than 80%) on a dry weight basis. It is often smoked, vaped, or ingested, especially for its intoxicating effect.
Medical Marijuana	Non-FDA-approved cannabis-based products where, despite limited clinical evidence regarding effectiveness, the patient's intended use is to prevent, treat, or mitigate a disease or alleviate its symptoms. Medical marijuana differs from recreational marijuana only in its intended use rather than its composition or formulation.

* Statutory definitions of these terms are also provided in the CCSS publication (reference 3).
Abbreviations: CBD, cannabidiol; CCSS, The Collaborative for CBD Science and Safety; FDA, U.S. Food and Drug Administration; THC, delta-9-tetrahydrocannabinol.
Source: Adapted from Reference 3.

In alignment with other professional and medical societies, GSA differentiates (a) medical products that are evidence-based and subject to FDA review and approval and (b) marijuana products that may be available in dispensaries but are not developed in accordance with rules for safety, efficacy, and Current Good Manufacturing Practices (CGMPs). GSA avoids use of the term "medical marijuana" and instead uses "medical use of cannabis" and "cannabis used for medical purposes" interchangeably to refer to cannabis-derived products that are sufficiently backed by clinical studies to be deemed safe and effective for medical use.

Methodology

In October 2020, GSA convened a 2-day virtual meeting addressing the topic of CBD safety in older adults from scientific, regulatory, and marketing perspectives.

GSA's Chief Executive Officer, James C. Appleby, BSPharm, MPH, ScD (Hon), moderated the meetings. Seven patient advocacy organizations and 10 professional societies participated in the discussions (Appendix A).

Objectives for the discussions were to address the safety and efficacy of cannabis-derived products used for medical purposes, including CBD, by:

- Raising awareness and understanding of key safety considerations.
- Discussing the state of the evidence offered in support of CBD products for medical purposes.
- Identifying additional research needs and barriers to evidence development.
- Identifying strategies to help mobilize organizations to take concrete steps designed to help older adults make informed decisions.

Prior to the meeting, GSA sent the latest literature and background resources to all participants to set the stage of the discussions. These included:

- Consumers for Safe CBD. *What Is CBD?* Video. A Project of the National Consumers League. 2020.
- Collaborative for CBD Science & Safety. Common Terminology & Glossary. August 18, 2020.
- Amy Abernethy, MD, PhD, Principal Deputy Commissioner, and Lowell Schiller, JD, Principal Associate Commissioner for Policy, U.S. Food and Drug Administration. FDA Is Committed to Sound, Science-Based Policy on CBD. FDA *Voices*. July 17, 2019.
- Kathleen T. Brady, MD, PhD. Medical marijuana: putting the cart before the horse. *American Journal of Psychiatry*. 2020;177(7)570–571.

In the first meeting, the experts presented information on CBD safety from various perspectives (Appendix B). In the second meeting, representatives of the participating organizations discussed the presentations and ideated on beneficial actions that their organizations could take to create conditions in which clinicians and older adults would have better access to information about the safety of CBD products. Subsequently, in preparation of the summary GSA staff conducted follow-up interviews with participating organizations to identify specific recommendations that could help advance the field.

The next section provides a summary of key themes and highlights from the expert presentations. The speakers sought to introduce participants to current CBD terminology, discuss the legal and regulatory status of CBD, describe what is known about the safety of CBD products, and describe high-priority areas of clinical research for addressing knowledge gaps related to safety and efficacy.

SUMMARY OF PROCEEDINGS

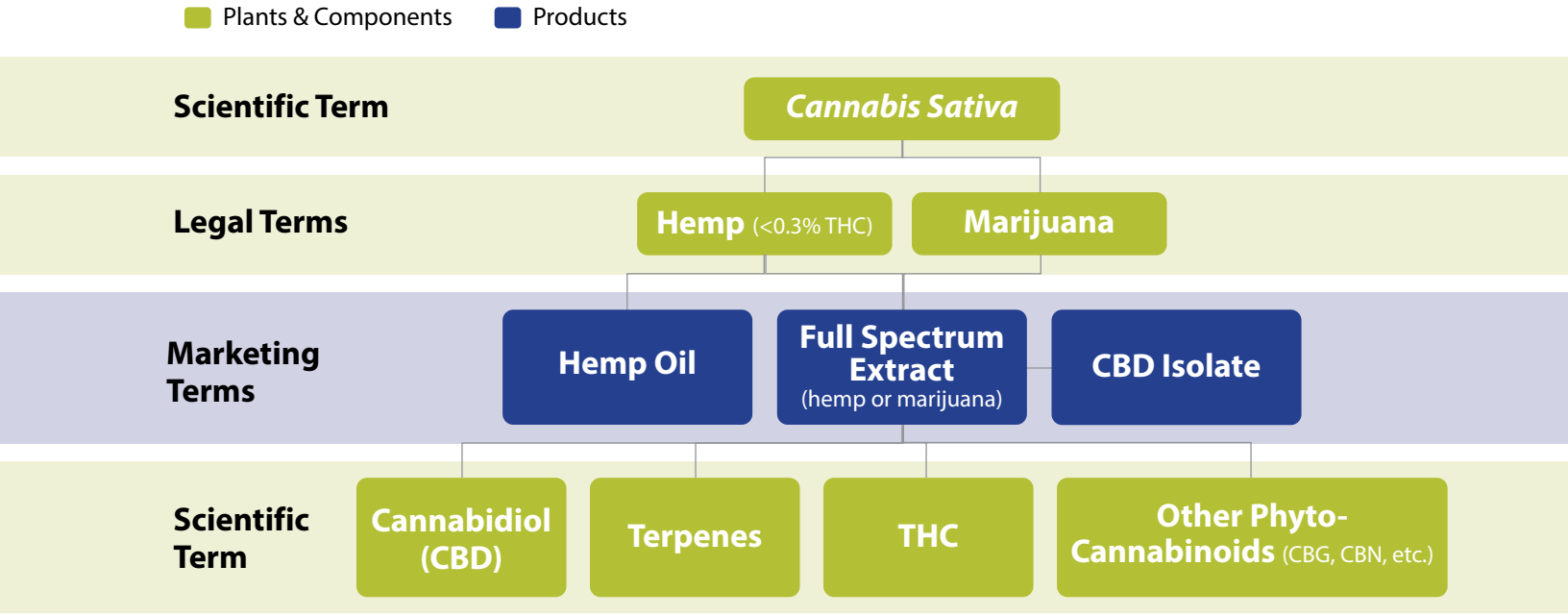
Terminology

Libby Baney, JD, Partner at Faegre Drinker, outlined how scientific, legal, and marketing terms (Appendix C) used to describe CBD have led to public confusion about this substance, what is permissible under state and federal laws, and whether CBD products are safe when used for medicinal purposes.

The uncertainty surrounding CBD products begins with scientific and legal distinctions. Various parts of the *Cannabis sativa* L. plant are treated differently in the law because of botanical analyses showing dissimilar pharmacologic activity of components in the flowers and flower buds, leaves, stems, and seeds of the plant.[4]

Cannabis sativa L. is the scientific name for the plant, explained Baney. As shown in Figure 1, *hemp* and *marijuana* are legal terms and, at the federal level, hemp is legal whereas marijuana is not. The plant also produces more than 100 cannabinoids that have been identified, including CBD, which has pharmacologic activity—that is, it affects drug receptors in the body—but produces no euphoria, and delta-9-tetrahydrocannabinol, or THC, which produces the "high" (euphoric or pleasure-inducing effects) associated with smoking, vaping, or ingestion of marijuana.[1,3]

Figure 1. Terminology Related to CBD Science and Safety



Abbreviations: CBD, cannabidiol; CBG, cannabigerol; CBN, cannabinol; THC, delta-9-tetrahydrocannabinol.

The cannabinoid distribution of a *Cannabis sativa* L. plant varies, with 21% of the cannabinoids found in the unseeded and seeded female flowers (buds)—primarily hemp—and 15% from unseeded buds, making them the predominant source for cannabinoid extraction and most suited for medical products, Baney said.[5,6]

Product names and terms used to refer to marketed products create another area of confusion about CBD, cannabis used for medical purposes, and derived products. For instance, the term *hemp oil* refers to extracts of the parts of the *Cannabis* plant used in hemp production, but the term *full-spectrum extracts* describes products that can be obtained during either hemp or marijuana production.[1]

The Status of CBD According to Federal and State Laws

Baney noted distinctions among common CBD-containing products, including recreational marijuana used for pleasure, hemp for industrial and commercial products, and cannabis used for medical purposes despite limited or no clinical evidence for its efficacy. Although states are regulating recreational marijuana and cannabis used for medical purposes in different ways at different levels (or doses for different people at different times), Baney said about three-quarters of states recognize recreational and/or medical use of cannabis, even as these products remain illegal at the federal level under Schedule I of the Controlled Substances Act.

Commercial use of hemp was recognized at the federal level in Farm Bills in 2014 and 2018. These statutes and subsequent regulations govern how *Cannabis sativa* L. can be grown, harvested, and used in production of hemp-based products.

The FDA has approved one CBD-based prescription drug, Epidiolex, which contains a purified form of CBD. Epidiolex is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older. The approval indicates the FDA has concluded that this drug is safe and effective for its intended uses based on data from controlled clinical trials. FDA-approved drugs must be manufactured according to CGMPs and meet FDA standards for quality, stability, and consistency.[7]

Currently, the FDA does not permit CBD to be used in dietary supplements and foods. Even so, the consumer market is awash with unapproved and illegally marketed CBD-based dietary supplements and foods. These unapproved cannabis-based products have not gone through rigorous clinical trials, and thus, their safety and efficacy are unknown. Further, although some states may have specific requirements for how cannabis-based products are manufactured, the FDA does not inspect these manufacturing sites for adherence to CGMPs.[8]

The current marketplace for CBD arose out of statutory changes to the Farm Bill in 2018. These changes included removing hemp from the Controlled Substances Act, which means that cannabis plants and derivatives—including CBD—that contain no more than 0.3% THC on a dry weight basis are no longer controlled substances under federal law.[9]

However, Baney said, a 30-milliter bottle of CBD could have up to 81 milligrams of THC. That amount is enough to produce a "high" and to cause a positive result on drug tests—a major problem for people in positions of employment where negative drug tests are required.

CBD products also present quality control quandaries for consumers and health professionals because of the lack of close FDA oversight. While prescription drug products are produced in manufacturing facilities that are inspected by the FDA for compliance with its CGMP criteria, dietary supplements are much more loosely regulated.

The FDA's Role in Developing Science-Based Policy

According to April Inyard Alexandrow, PhD, Lead for the FDA's Cannabidiol Policy Working Group, the marketplace for products containing CBD is evolving. In a video presentation, Alexandrow reiterated the need for science in developing new medical products that would be eligible for FDA approval. The FDA seeks to ensure that consumers know about medical products that put their health at risk and to close knowledge gaps about safety and potential therapeutic benefits, she said.

The FDA continues to gather information about how it can best regulate medical products containing CBD, including reopening its public docket, Information on CBD Data Collection and Submission, in March 2020. The agency recognizes that there is substantial public interest in cannabis and cannabis-derived products for medical purposes and the many unanswered questions about the science, safety, and quality of non-FDA-approved products containing CBD. Key questions that the FDA has sought to address include[10,11]:

- What happens if people use CBD daily for sustained periods of time?
- What level of intake triggers the known risks associated with CBD?
- How do different methods of exposure affect intake (e.g., oral consumption, topical use, smoking, vaping)?
- What is the effect of CBD on the developing brain (such as in children who take CBD)?
- What are the effects of CBD on the developing fetus or breastfed newborn?

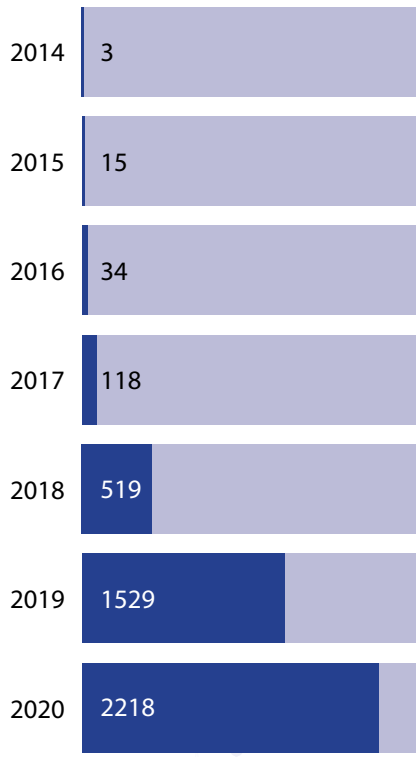
- How does CBD interact with other herbs, botanicals, or prescription and over-the-counter medications?
- Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?
- Are there differing safety concerns for use in certain animal species, breeds, or classes?
- Are any residues formed in edible tissues of food-producing animals?

Pharmacologic Risks Related to Changes in Physiology

When CBD is consumed as an ingredient in a non-FDA-approved medical product, it can produce acute impairment of attention, memory, verbal learning, executive function, and psychomotor function.[12] Exactly how aging-related changes in physiology affect the responses of older adults to CBD requires further study.[1,13]

According to William J. Lynch Jr., BPharm, RPh, Clinical Pharmacist for Jefferson Health and Adjunct Professor at Rowan University School of Osteopathic Medicine, one indicator of potential safety concerns related to non-FDA-approved CBD products has been the sharp rise in calls to poison control centers, which rose from 3 calls nationally in 2014 to 2,218 calls in 2020 (Figure 2).[14]

Figure 2. Cannabidiol Cases Reported Annually to U.S. Poison Control Centers



Source: Reference 14.

Lynch also outlined other potential adverse reactions to non-FDA-approved CBD products, including insomnia, diarrhea, fatigue, malaise, rash, vomiting, elevations in the transaminase enzymes of the liver, and infections.[4,15] "It's important to know these effects because as pharmacists and physicians, we might modify a person's medications if we found elevated liver function tests, for example—especially for older adults," Lynch said. "There also are many drug interactions with CBD that could cause increased clotting or bleeding, hepatotoxicity, or changes in metabolism that would require doses of other medications to be changed. CBD is not necessarily benign."

Primary safety concerns include the lack of patient information and physician advice that would be available for an FDA-approved drug product, as well as lack of documentation on potential drug interactions. Another concern is the presence of certain inert (nonactive) ingredients in non-FDA-approved CBD products, such as sesame seed oil and alcohol, which may trigger side effects. In addition to consulting with clinicians before considering use of CBD products for medical purposes, Lynch recommended that consumers ask for a certificate of analysis when they purchase a non-FDA-approved CBD product. He also suggested that older adults create a list of all their medications, vitamins, and supplements—with doses and how often they are taken—and provide a copy to all their physicians and, when appropriate, a close family member.

Unmet Clinical Needs That Lead to CBD Use

Two speakers discussed how clinical researchers are seeking to address the unmet needs of individuals affected by pain, insomnia, anxiety, neuropsychiatric symptoms of dementia, and a variety of motor and neuropsychiatric symptoms of Parkinson's disease.

Brent P. Forester, MD, MSc, Chief of the Division of Geriatric Psychiatry at McLean Hospital and Co-President of the American Association for Geriatric Psychiatry, recognized that clinicians have limited data to share with patients about the safety and efficacy of non-FDA-approved CBD products for conditions that are difficult to manage, including anxiety or agitation, depression, and behavioral symptoms of Alzheimer's disease. One reason for limited research may be that the current regulatory environment (in which cannabis and most derivative products are treated as Schedule I controlled substances) makes it very challenging to do research on controlled substances; research is easier on hemp-based compounds, Forester said.

Andrew Koemeter-Cox, PhD, Associate Director of Research Programs with The Michael J. Fox Foundation for Parkinson's Research, shared that individuals with Parkinson's disease are desperate to try any avenue to treat the nonmotor symptoms of their condition. However, clinical evidence on CBD use in this patient population is extremely limited. Koemeter-Cox attributed this to small sample sizes, the heterogeneity of cannabis products, and treatment paradigms used in these trials. He indicated that about a quarter of patients with Parkinson's disease have used or are using non-FDA-approved cannabis-based products for one or more symptoms—but often without guidance of any kind, clinical or otherwise.

"Research as Marketing"

According to Theodore L. Caputi, MPH, President and CEO of Data Science Solutions, instead of addressing the dearth of clinical research in the field, some companies focused on selling non-FDA-approved cannabis-based products sponsor low-quality studies to generate data that they can use to promote a perception of safety among consumers. Describing a phenomenon that he calls "research as marketing,"[16] Caputi noted, "[These] companies tend to sponsor weaker, observational, and lower-level clinical studies that are highly likely to produce positive results, and these are then publicized widely. We're left with simply not knowing if CBD or other cannabis-derived products are safe or effective for treating almost any condition."

"If a layperson were to read [such a company's] marketing materials, they might well be led to believe that the safety and efficacy of marijuana or CBD is a matter of scientific fact even though it's just not," Caputi said. Yet other than the few cannabis-derived prescription medicines approved by the FDA and their narrow indications, safety and efficacy are unproven for all the other benefits claimed for CBD. "What that means is that for all the other diseases that are commonly linked to CBD use—such as anxiety, pain, Parkinson's disease, and cancer—there is no telling if CBD or any other cannabis-derived products are actually safe and effective."

Existing Barriers to More Robust CBD Research

According to Wade Ackerman, JD, FDA Regulatory Partner at Covington & Burling, medical research can play an important role in mitigating public health concerns about the safe use of CBD products for medical purposes. Bolstering research on CBD can also help society realize CBD's potential as a medical product for serious conditions and vulnerable populations.

Ackerman listed three primary barriers for researchers wanting to conduct sound research into CBD use:

1. State laws that have legalized cannabis for medical purposes with little incentive to pursue rigorous research and development.
2. The complicated legal and regulatory history of cannabis products in the United States.
3. Availability of CBD with unapproved therapeutic claims that undermine the FDA's new drug approval process.

Ackerman delineated examples of policies to advance research and development of some medications. Congress, recognizing a need for more investment in research and approved therapeutic options for patients with rare diseases and conditions, passed the Orphan Drug Act of 1983 to stimulate development. "This shows that you can come up with policies that through advanced medical R&D help products go through the FDA process and into patients' hands," Ackerman said.

ACTIVITIES FOR CONSIDERATION: SUMMARY OF DISCUSSIONS

Following the expert presentations, the meeting participants brainstormed potential activities for advancing the safety of CBD use in older adults through the following avenues: Research, Clinical Education, and Awareness-Raising and Advocacy. In addition, GSA conducted targeted 30-minute interviews to probe further on ideas proposed by participants. Table 2 summarizes the high-level ideas shared by the various stakeholders; a more detailed description of key ideas and tactics follows.

Table 2. Participant Ideas for Advancing CBD Safety

Research	Clinical Education	Awareness-Raising and Advocacy
Collect data on clinical reasons older patients are motivated to use CBD	Conduct a qualitative survey across multiple professional societies to identify how care teams can be better supported in counseling older adults in the absence of clinical evidence	Disseminate and raise awareness about a common set of terminology that distinguishes CBD from cannabis for medical purposes
Standardize the quality of the CBD specimen being researched, the concentration of CBD, the dosage, and outcomes being measured in clinical studies	Develop clinical guidance on ways to increase communication between care teams and patients about CBD to support informed decision-making	Counter misleading claims about CBD products through consumer-focused channels such as blogs, websites, podcasts, and social media
Train and support early-career researchers in developing high-quality clinical protocols for CBD safety research and navigating regulatory constraints	Develop evidence briefs addressing common clinical questions and misconceptions by therapeutic need	Develop a regulatory track for CBD and address the discrepancies between federal and state laws regarding CBD products
Engage with the National Institutes of Health, National Institute on Aging, Substance Abuse and Mental Health Services Administration, and Patient-Centered Outcomes Research Institute to increase coordination at the federal level on a national CBD research agenda and funding for large-scale studies.	Develop continuing professional education programs focused on developments in CBD science, including events at professional society annual meetings	Develop state-by-state resources on CBD to support constituents and members

Abbreviation: CBD, cannabidiol.

Research

Most participants agreed that CBD science trails behind both CBD policy and product marketing. Participants felt that there was a need to build out evidence about the safety profile and efficacy of CBD as it relates to pain, anxiety, insomnia, Parkinson's disease, dementia, and other conditions for which CBD is considered a potential therapeutic for unmet needs. Several organizations recommended more research on the topical use of CBD in the form of creams, lotions, and ointments, because some older adults will try topical products for relief from arthritis pain and other types of chronic pain. Organizations also expressed interest in the relationship between use of CBD in older patients and falls. Furthermore, the group recommended incorporating data points on the clinical reasons older patients were motivated to use CBD, comorbid conditions, social determinants of health, and quality of life in the design of future CBD trials.

One of the participating patient advocacy organizations suggested that clinical studies on CBD as a medical product need to be better standardized; variation across the quality of a CBD specimen being researched, the concentration of CBD, the dosage, and the clinical outcomes being measured would make it difficult to compare results across studies and therapeutic areas. A multidisciplinary consensus meeting of experts could lead to some agreed-upon standards for designing clinical trials focused on CBD safety. Pharmaceutical companies with research experience on the topic of CBD could also lend expertise in trial design and research.

Although participants agreed there was a dearth of clinical research related to CBD, there was not consensus on the reasons for this lack. One participant suggested that although grants for CBD research are available, few researchers submit high-quality proposals for grant opportunities. A suggested solution would be to develop fellowships or programs that could train early-career researchers on how to develop high-quality clinical protocols on CBD and subsequently help navigate potential regulatory constraints (e.g., scheduling of specimens).

When discussing research collaborations, one participant suggested there was room to have a national discussion on research priorities for CBD. Stakeholders could work together to engage the National Institutes of Health, National Institute on Aging, Substance Abuse and Mental Health Services Administration, and Patient-Centered Outcomes Research Institute to increase coordination among federal agencies on the topic of CBD. Coordination would help address barriers to research, such as certain CBD research specimens are classified as Schedule I, and would facilitate funding for larger, multisite trials.

Clinical Education

Meeting participants agreed that while clinicians are often expected to be a main source of information on the safety of CBD products for patients, and frequently receive referrals from patient advocacy groups, there is limited clinical training available on CBD due to the evolving evidence base. Despite these circumstances, stakeholders at the meeting expressed that it is important to support care teams in being able to counsel older patients, who are seeking reliable sources of information, through the development of new educational opportunities and clinical tools.

Participants suggested conducting qualitative surveys with the memberships of various professional societies (including but not limited to clinicians and allied health professionals) to identify unmet needs and specific ways those needs could be addressed either by individual organizations or in collaboration. Even with a limited evidence base, participants felt that a variety of approaches could help support care teams in counseling older patients, including the following:

- Clinical guidance addressing best practices for communicating with older adults about a shifting evidence base to support informed decision-making.
- Evidence briefs addressing common clinical questions and misconceptions according to therapeutic need.
- Continuing professional education programs focused on developments in CBD science, including events at professional society annual meetings as well as monthly webinars.
- Professional society and patient advocacy newsletters providing summaries of the latest evidence on CBD in a convenient format.

Awareness-Raising and Advocacy

Participants agreed that awareness-raising and advocacy are instrumental to moving both the research agenda and quality of clinical counseling forward. Participants stated that both the public and policymakers should understand more about what CBD is and is not, its risks and benefits, and how it differs from the medical use of cannabis. In addition, existing policy statements on cannabis for medical purposes do not address CBD-related concerns and use. To address this challenge, raising awareness about how CBD is defined would help individuals better understand the potential safety risks of CBD. As described in Table 1, CCSS has developed a glossary of terms that is intended to provide a common framework for discussing CBD research, safety, and quality.[3]

In a similar vein, participants deemed it important to actively counter misleading marketing claims made by certain manufacturers of CBD products. While the FDA has consistently sent warning letters to companies seeking to mislead the public, organizations in the field of aging and patient advocacy groups are ideally positioned to offer reliable information for older patients and to help translate scientific research for consumers.[17] Some of the meeting participants regularly engage consumers regarding questions related to clinical safety issues via blogs and websites.

CONCLUSION

In spite of a plethora of CBD products, there is also a lack of high-quality clinical research studies to support their use. Despite the scarcity of evidence, older adults are interested in using, or are already using, CBD products to alleviate symptoms from numerous diseases, undeterred by the risks. Thus, it is urgent to address current gaps in knowledge about the safety of CBD products in older adults through scientifically rigorous research.

Professional societies in the field of aging and patient advocacy groups are ideally positioned to advocate for public policies that support more research on CBD safety and efficacy, as well as to encourage more professionals to enter this area of research. Evidence from future CBD trials can lead to more FDA-approved CBD-based therapies, improved clinical treatment guidelines, and clearer consumer information.

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APPENDIXES

Appendix A. Meeting Participants

Professional Organizations	Organization Representatives
Patient advocacy organizations	
ALZHEIMER'S ASSOCIATION	Rebecca M. Edelmayer, Director of Scientific Engagement
ANXIETY AND DEPRESSION ASSOCIATION OF AMERICA	Susan K. Gurley, Executive Director
ARTHRITIS FOUNDATION	Anna Hyde, Vice President of Advocacy and Access
EPILEPSY FOUNDATION	Abbey Roudebush, Senior Manager of Government Relations and Advocacy
THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH	Andrew Koemeter-Cox, Associate Director of Research Programs Aaron Polacek, Public Policy Officer
NATIONAL CONSUMERS LEAGUE	Jeanette Contreras, Director of Health Policy
NATIONAL COUNCIL ON AGING (also participated in discussions with professional societies)	Kathleen A. Cameron, Senior Director of the Center for Healthy Aging
Professional societies	
AMERICAN ACADEMY OF NEUROLOGY	Matt Kerschner, Government Relations Manager
AMERICAN ASSOCIATION FOR GERIATRIC PSYCHIATRY	Brent P. Forester, Co-President Christopher N. Wood, Executive Director
AMERICAN ASSOCIATION OF NURSE PRACTITIONERS	Jan Towers, Senior Policy Advisor
AMERICAN PHARMACISTS ASSOCIATION	Karin Bolte, Director of Health Policy Johanna Katroscik, Pharmacy Student
AMERICAN SOCIETY ON AGING	Leanne Clark-Shirley, Vice President of Programs and Thought Leadership
GERONTOLOGICAL ADVANCED PRACTICE NURSES ASSOCIATION	Jennifer Kim, Treasurer, and Assistant Professor of Nursing at Vanderbilt University School of Nursing
THE GERONTOLOGICAL SOCIETY OF AMERICA	Patricia M. D'Antonio, Vice President of Professional Affairs
LEADINGAGE	Cory Kallheim, Vice President of Legal Affairs and Social Accountability
NATIONAL ASSOCIATION OF SOCIAL WORKERS	Chris Herman, Senior Practice Associate—Aging
NATIONAL COUNCIL FOR BEHAVIORAL HEALTH	Samantha Holcombe, Senior Director of Practice Improvement
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	James C. Appleby, Chief Executive Officer
	Karen K. Tracy, Vice President, Strategic Alliances and Integrated Communications
	Judit Illes, Director, Strategic Alliances

Appendix B. Expert Presentations

Topics	Presenters
Communicating About Medical Cannabis and CBD to Consumers and the FDA's Role in CBD Policy	Libby Baney, JD, Partner, Faegre Drinker
FDA's Role in Driving Sound Science-Based Policy on CBD	April Inyard Alexandrow, PhD, Lead for Cannabidiol Policy Working Group, FDA Office of the Commissioner, Office of Clinical Policy and Programs
Fireside Chat: Research and Marketing Practices for CBD Impacting Consumer Safety	Theodore L. Caputi, MPH, President and CEO, Data Science Solutions LLC William L. Lynch Jr., RPh, BPharm, Clinical Pharmacist, Jefferson Health, and Adjunct Professor, Rowan University School of Osteopathic Medicine
Fireside Chat: Addressing the Unmet Clinical Needs of Patients and Families Through New Research Programs	Brent P. Forester, MD, MSc, Chief of the Division of Geriatric Psychiatry, McLean Hospital, and Co-President, American Association for Geriatric Psychiatry Andrew Koemeter-Cox, PhD, Associate Director of Research Programs, The Michael J. Fox Foundation for Parkinson's Research
Policies to Accelerate CBD Research to Encourage Medical Innovation	Wade Ackerman, JD, FDA Regulatory Partner, Covington & Burling LLP

Appendix C. Glossary of Terms

Science

Cannabidiol: Commonly referred to as CBD, cannabidiol is a cannabinoid in Cannabis that has pharmacologic effects but no psychogenic effects. Cannabinoids can be naturally occurring or synthesized. The U.S. Food and Drug Administration has recognized four cannabinoids for specific indications (uses). Epidiolex is the only Cannabis-derived cannabidiol product; it is indicated for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex. Synthetic cannabinoid-related products on the U.S. market are dronabinol (Marinol, Syndros) and nabilone (Cesamet).

Cannabinoids: Organic components in Cannabis that act as drugs by causing pharmacologic effects through interactions with receptors in the central nervous system (brain and spinal cord) and immune system of the human body. The more than 100 Cannabis cannabinoids have a wide variety of effects in humans, including psychogenic effects on the brain. Endocannabinoids are related compounds made in the human body.

Cannabis: Generic term for all parts of the *Cannabis sativa* L. plant. Two forms of *Cannabis sativa* are described legally: hemp and marijuana.

Terpenes: Aromatic (creating a distinctive scent) organic compounds (hydrocarbons) occurring mostly in plants, including Cannabis; these form building blocks for making other, more complex compounds.

THC: An abbreviation for delta-9-tetrahydrocannabinol, THC is the main psychoactive cannabinoid in Cannabis and is responsible for the drug's euphoric or pleasure-inducing effects.

Law

Dietary supplements: Ingredients in the diet such as vitamins, minerals, herbs, amino acids, and enzymes. Regulated by the U.S. Food and Drug Administration under the Dietary Supplement Health and Education Act of 1994, dietary supplements are marketed in forms such as tablets, capsules, softgels, gelcaps, powders, and liquids.

Hemp: A type of *Cannabis sativa* L. grown for its seeds and fibrous materials (roots and stems) that are used in manufacturing of products such as rope. As defined under Farm Bills passed in 2014 and 2018, hemp is legal in the United States but must contain less than 0.3% of THC by dry weight.

Marijuana: At the federal level, "marihuana" means all parts of the *Cannabis sativa* L. plant, including the seeds and resin where cannabinoids occur. Other than Cannabis components that fall into the hemp category, *Cannabis sativa* L. is categorized by the U.S. Drug Enforcement Administration as a Schedule I controlled substance, which makes it illegal and indicates that the drug has a high potential for abuse and no currently accepted medical use. On the street, marijuana usually refers to the dried resinous flower buds and leaves of the plant; it is smoked, vaped, or ingested, especially for its intoxicating effect.

Medical marijuana: Despite illegality at the federal level and lack of sound clinical evidence, marijuana is increasingly recognized for medical uses at the state level. About three-quarters of states in the United States recognize medical uses of marijuana. These products are not approved by the U.S. Food and Drug Administration. Some states limit the amount of THC that can be in products used for medical marijuana, but in many states, the same products can be used for medical or recreational purposes.

Recreational marijuana: About one third of states in the United States have legalized marijuana for nonmedical use, generally to induce pleasure, euphoria, or relaxation, or to induce sociability. As discussed under the medical marijuana entry, the same products can be used for medical or recreational purposes; the difference is the person's purpose in using the product.

Marketing

Marketers use many brand names and other terms in promoting their products to the public. These can further confuse consumers and health professionals seeking clarity when the product names and terms are not aligned with the scientific and legal terms as defined in this glossary. Examples of terms used for marketing Cannabis products to the public are hemp oil, full spectrum extract (hemp or marijuana), CBD isolate, and Cannabis terpenes.

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