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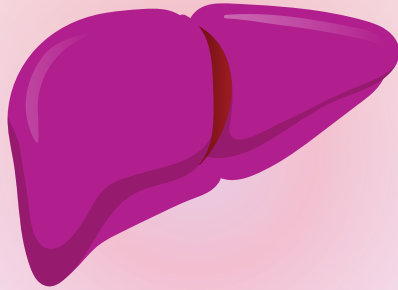
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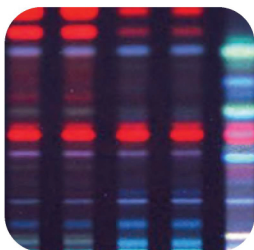


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## PUBLISHER'S NOTE

# Progress on Women's Health

**I**n this month's issue of *Nutritional Outlook*, Judy Blatman writes about menopause (page 32), the way it impacts women's lives, and the dietary supplement ingredients that may help them better navigate this difficult stage. Menopause has become a symbol for just how broadly neglected women's health needs are in health-care. Despite being a major physiological transition, many women face menopause in isolation, not fully understanding what they are experiencing or how to address symptoms.

According to a report from Gen M, which was recognized as *Nutritional Outlook's* Best of the Industry: Service Provider in 2023, 41% of menopausal women feel "lonely, invisible, irrelevant, and dispensable," due to the lack of information and resources available to them. That same report states that of the 48 possible symptoms related to menopause, 51% can only name three. That means that at least half of women are experiencing menopause symptoms and don't know it. Gen M helps women and their support systems navigate store aisles to find menopause-supportive products with its Menopause Friendly tick symbol. Of course, that is just one area in which women need help.

A recent roundtable conducted in partnership with Women in Nutraceuticals discussed the many areas in which the Women's Health Initiative – the largest longitudinal study of its kind on women using hormone therapy – offered some answers and raised new questions about menopause. With women largely excluded from clinical trials from the 1970s through the 1990s, much more research is necessary to make up for the decades of insights lost that could help the healthcare and wellness industries better address menopause and other health risks affecting women.

While pharmaceutical interventions exist in treating symptoms of menopause, Blatman's article points out that many women prefer to try a more natural approach before resorting to hormone therapy, for example. Dietary supplement brands are answering the call, offering a number of solutions that may improve menopausal women's quality of life, and adding to the body of research that demonstrate how specific herbs, vitamins, and minerals impact women at this vulnerable point of their lives. It's encouraging to see how menopause is becoming destigmatized and that women have greater access to products that may help them through.

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††Paulussen, K. J. M., Askow, A. T., Deutz, M. T., et al. (2024). Acute Microbial Protease Supplementation Increases Net Postprandial Plasma Amino Acid Concentrations after Pea Protein Ingestion in Healthy Adults: A Randomized, Double-Blind, Placebo-Controlled Trial. The Journal of Nutrition (published online, in press).

‡Garvey, S. M., et al. (2022). Gut Microbes, 14(1), 2122668.





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**SUBSCRIPTIONS:** For subscription and circulation information: Nutritional Outlook, P.O. Box 457, Cranbury, NJ 08512-0457, or e-mail [mmhinfo@mmhgroup.com](mailto:mmhinfo@mmhgroup.com).

**CHANGE OF ADDRESS:** Send change of address to Nutritional Outlook, 2 Clarke Drive, Suite 100, Cranbury, NJ 08512, or send change via e-mail to [mmhinfo@mmhgroup.com](mailto:mmhinfo@mmhgroup.com). Allow four to six weeks for change. Publications Mail Agreement No. 40612608. Return all undeliverable Canadian addresses to: IMEX Global Solutions, P.O. Box 25542, London, ON, N6C 6B2, Canada. Canadian GST number: R-124213133RT001.

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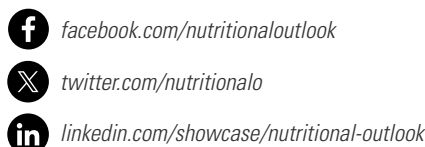
Nutritional Outlook (ISSN 1098-1179) is published monthly, except combines Jan/Feb and Jul/Aug, by MJH Life Sciences, 2 Clarke Drive, Suite 100, Cranbury, NJ 08512. Periodicals Postage paid at Cranbury, NJ and additional mailing offices.

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## PODCAST

### Demystifying Prebiotics and Postbiotics

This episode of the Nutritional Outlook Podcast looks back on a webcast *Nutritional Outlook* hosted in May, called “Demystifying the Prebiotic and Postbiotic Markets.” The International Probiotics Association’s director of education and communication, Sandra Saville, RD, and scientific director, Jessica A. Younes, PhD, provided expert insights.



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For more fun facts, visit [nutritionaloutlook.com](http://nutritionaloutlook.com)

Source: “Oldest known wine-making facility” found in Armenia. *BBC*, January 11, 2011. [https://www.bbc.com/news/world-europe-12158341#:~:text=The%20world's%20earliest%20known%20wine,in%20the%20south%20Caucasus%20country.\(Accessed 2024-09-20\)](https://www.bbc.com/news/world-europe-12158341#:~:text=The%20world's%20earliest%20known%20wine,in%20the%20south%20Caucasus%20country.(Accessed%202024-09-20))



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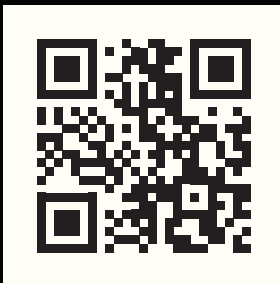
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# Hemp Uncertainty

Complications continue to arise in the sale of hemp-derived cannabinoids.



Sebastian Krawiec  
MANAGING EDITOR

“  
The  
reactionary  
policies of  
the states  
highlight  
the failures  
of federal  
regulators  
and  
legislators  
to take  
meaningful  
actions.”

**IN THIS MONTH'S** issue of *Nutritional Outlook*, assistant editor Erin McEvoy writes about the state of hemp regulations (Page 22). The hemp-derived cannabinoid space has been developing rapidly to the dismay of state and federal regulators as well as public health advocates. This is particularly true with regard to intoxicating cannabinoids such as delta-8 and delta-10 THC, which have quickly proliferated to food and beverage products. While some manufacturers responsibly market products containing intoxicating cannabinoids, major concerns have been raised around copycat products that imitate popular CPG brands, which can mislead consumers and lead to unintentional consumption in children.<sup>1</sup>

This has led to states imposing or attempting to impose regulations on intoxicating cannabinoid products. Many of these laws negatively impact sellers of non-intoxicating cannabinoids such as cannabidiol (CBD). This is particularly true in California<sup>2</sup> where Governor Gavin Newsom proposed emergency regulations that would prohibit any traces of THC in hemp-derived products, ultimately impacting manufacturers and retailers of full spectrum hemp extracts that meet the federal threshold

for THC of 0.3 % by dry weight (See Page 12).

The reactionary policies of states highlight the failures of federal regulators and legislators to take meaningful actions that would lead to the oversight of hemp-derived cannabinoid products. While manufacturers exploit a so-called loophole from the 2018 Farm Bill, which made hemp legal to cultivate and harvest, the U.S. Food and Drug Administration has refused to develop a regulatory framework for the sale of hemp-derived extracts, citing drug preclusion. Some argue that the lack of regulation even precipitated the growth of intoxicating cannabinoids synthesized from other hemp-derived cannabinoids as suppliers tried to salvage their inventory in the face of plummeting prices.<sup>3</sup>

Complicating matters in the states is the patchwork of recreational and medicinal cannabis laws. In California, for example, the legal cannabis industry is antagonistic to hemp-derived products, viewing them as upstarts that are skirting regulations while they've worked hard at legitimacy. This may be particularly true now with the advent of intoxicating cannabinoids. But do all hemp-derived cannabinoid products belong in dispensaries?

At the time of publication, Congress has failed to meet its deadline on passing the 2024 Farm Bill, which was September 30. To what extent that bill will help or complicate the hemp marketplace is not yet clear, but now more than ever, the industry needs progress on this topic. *Nutritional Outlook* will continue to monitor the regulatory environment and keep you informed. ■

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Below is a roundup of the latest news surrounding the regulation of hemp-derived cannabinoid products as of the publication of this issue.

Stay Informed!

You can continue to follow these stories and the latest developments in hemp-derived cannabinoid regulations at **NUTRITIONALOUTLOOK.COM/NEWS/REGULATORY**



## California Assembly Bill That Would Impose Regulations on Hemp-Derived Cannabinoids Fails to Pass State Senate

**ON AUGUST 15, 2024** a California Assembly bill (AB 2223) that would limit certain cannabidiol (CBD) products to a maximum of 0.25 milligrams of tetrahydrocannabinol (THC) per serving per package, or 1mg of THC per final product, as well as allow licensed dispensaries to sell hemp products, has been “held under submission” in the state’s Senate Committee on Appropriates, effectively killing its progress in this legislative session. Industry advocates such as the U.S. Hemp Roundtable celebrated the bill’s failure.

However, the group cautioned that more work will be necessary to prevent future efforts and to promote safety and quality across the hemp industry. The U.S. Hemp Roundtable stated in a press release: “The war on hemp continues on Capitol Hill and in state capitals across the country. Moreover, in California, challenges remain. While the vast majority of hemp farmers, product manufacturers and retailers are small and family businesses who play by the rules and hold themselves to the highest standards, bad actors in our industry continue to manufacture products without quality control, label and package them insufficiently, and illegally target children. We also need to do a better job to promote equitable solutions for the entire cannabis industry.”

In a statement released on August 14, 2024, the U.S. Hemp Roundtable’s general counsel, Jonathan Miller, criticized the legislation and urged stakeholders to reach out to representatives to reject the bill. He explained that AB 2223 undermined previous efforts for a “balanced, rational and

responsible framework to legalize hemp CBD products in California,” namely AB 45. That bill was passed into law in October 2021, and promised to “create a registration process, under the State Department of Public Health, for hemp manufacturers who produce specified products that include industrial hemp or who produce raw hemp extract, as defined, including requirements for testing and labeling on products.”

“Unfortunately, [Assembly member Aguiar-Curry’s] new bill, AB 2223, introduced this year, took a big step backward. The bill included outrageous requirements that would result in the ban of 90-95% of hemp products for retail sale – including most non-intoxicating CBD products that were the explicit focus of passage of AB 45. Hemp advocates were met with continual promises – both privately and during public hearings – that our concerns would be addressed, that the language in AB 2223 was just a starting point of the discussion. The hemp industry provided legislators and the Administration with scientific and economic studies to bolster our arguments,” said Miller in his statement. “Yet just within the past few weeks, the California Department of Cannabis Control dropped a bomb on the discussions. In 41 pages of new ‘technical’ amendments, the agency proposed that all hemp products with any THC in them – again, meaning nearly every hemp product – come under their purview and therefore be banned from retail sale.”

Advocates for cannabis industry cultivators have also opposed the proposed legislation. The Origins Council, a group that claims to

represent “800 small and independent cannabis businesses in rural legacy producing counties throughout California,” for example, wrote a letter to Aguiar-Curry in April addressing their concerns and proposing amendments. The letter states: “The majority of our comments focus on AB 2223’s proposal to incorporate hemp into legal cannabis products. If not developed with extreme care, we believe this proposal risks an industry-wide shift towards chemically-converted and synthetic cannabinoids with unclear safety profiles. These loopholes would both significantly undermine small cannabis cultivators, and compromise existing quality control practices in the cannabis supply chain that provide protection to consumers. Additionally, unless and until cannabis and hemp cultivation are regulated at parity, the incorporation of naturally-occurring and concentrated delta-9 THC and comparable cannabinoids from hemp into the cannabis supply chain further threatens to dramatically undermine licensed cannabis cultivators who are currently regulated to a much high degree than hemp cultivators growing the same plant.”

Additionally, retailers of hemp-derived cannabinoid products and patient advocates were critical of the legislation’s stating that the push to have hemp products sold in licensed dispensaries would hurt retailers for whom licensure is financially difficult to obtain as well as customers who rely on non-intoxicating hemp products for their health. Limiting access to hemp-derived cannabinoid products to dispensaries in effect reduces patient and consumer access to said products because there will be fewer retailers to choose from and prices will likely increase.



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## Governor Newsom Issues Emergency Regulations Banning Any Level of THC in Hemp-Derived Food and Beverage Products

**CALIFORNIA GOVERNOR GAVIN NEWSOM** has issued proposed emergency regulations that would require food, beverages and dietary products that contain industrial hemp to have no detectable levels of delta-9 THC or other intoxicating cannabinoids per serving, limit the number of servings for hemp products to five, and create a minimum age of 21 to purchase hemp products. The rationale for the regulations, proposed by the California Department of Public Health (CDPH), is to protect youth from adverse effects related to products such as delta-8 THC.

"Intoxicating industrial hemp products can cause illness and injury to California consumers," said Tomás Aragón, CDPH director and state public health officer, in a statement. "We are working to ensure products in the marketplace comply with state laws that protect consumers against these public health risks and have proposed emergency regulations that will improve protections for consumers."

The regulations will take effect immediately upon approval from the Office of Administrative Law. Sellers will have to implement purchase restrictions and remove consumable hemp products with any detectable levels of THC from shelves. If the law is approved, regulators that include the Department of Public Health, the Department of Cannabis Control, the California Department of Alcoholic Beverage Control (ABC), the California Department of Tax and Fee Administration (CDTFA), and state and local law enforcement officials, will begin immediate enforcement action.

This action comes not long after the failure of AB 2223 to pass the state's senate. Industry has been highly critical of the bill, which would have placed burdensome restrictions on hemp products, hurting manufacturers, retailers, and consumers.

"Today's 'emergency' action by Governor Newsom is a betrayal of California hemp farmers, small businesses, and adult consumers. After having supported AB 45, which created a

sound regulatory framework for the manufacture and sale of hemp products, Newsom's Administration fell on the job and failed to take any steps to enforce it," said Jonathan Miller, general counsel for the U.S. Hemp Roundtable, in a statement. "Now, instead of addressing legitimate regulatory concerns shared by all good actors in the cannabis space — such as establishing reasonable policies to keep intoxicating products out of the hands of children — Governor Newsom instead has proposed a complete retail prohibition on 90-95% of popular hemp products for adults, including most non-intoxicating CBD products that he purports to support in his public communications. And in the middle of massive California budget deficits, he is unnecessarily throwing away nearly a quarter billion dollars in tax revenue from legitimate small businesses. We will be exploring all legal options in the coming days with California hemp farmers and businesses that comprise the multi-billion-dollar industry that this action would destroy."



## Missouri's Health Department to Begin Enforcement Action Against Food Products Containing Unregulated Psychoactive Cannabis

**MISSOURI'S DEPARTMENT** of Health and Senior Services (DHSS) is on track to "embargo and condemn" products that contain intoxicating cannabinoids starting September 1, 2024 in accordance to an executive order signed by the state's governor, Michael L. Parsons. Executive Order 24-10 was issued on August 1st and pertains to "psychoactive cannabis products include delta-8 tetrahydrocannabinol (THC), delta-10 THC, hexahydrocannabinol (HHC), tetrahydrocannabinol (THC-O), tetrahydrocannabiphoral (THCP), tetrahydrocannabivarin (THCV), and other similar compounds."

In addition to asking DHSS to "embargo and condemn unregulated psychoactive cannabis products," the order also directed the Missouri Division of Alcohol and Tobacco Control (ATC) to amend its regulations to



prohibit the sale of these products in liquor-licensed facilities. The State's Secretary of State Jay Ashcroft denied emergency rulemaking submitted by ATC in response to the executive order, but that will have no impact on the DHSS. ATC continues to pursue new rulemaking but will go through

the regular channels which can take up to six to eight months.

Missouri's DHSS states that there has been a 600% increase in the number of children ages five and under who have experienced cannabis poisoning that resulted in emergency room visits or hospitalizations since 2018. Many of these products are copycats of popular foods or candies such as Life Savers. This has been the case nationwide, with the U.S. Food and Drug Administration sending out warning letters to multiple brands selling copycat products containing intoxicating cannabinoids.

The provisions set forth in the executive order do not apply to products under the control of the Division of Cannabis Regulation under Article XIV of the Missouri Constitution.

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## Missouri Hemp Trade Association Files Lawsuit Against State's Department of Health Over Ban on Psychoactive Hemp-Derived Cannabinoid Products

**FOLLOWING AN EXECUTIVE ORDER** from Missouri Governor Michael L. Parson, the Missouri Department of Health and Senior Services (DHSS) has begun a policy to “embargo and condemn” “unregulated psychoactive cannabis products.” The order pertains to products that contain “delta-8 tetrahydrocannabinol (THC), delta-10 THC, hexahydrocannabinol (HHC), tetrahydrocannabinol (THC-O), tetrahydrocannabinol (THC-P), tetrahydrocannabinol (THC-V), and other similar compounds.”

In response, on August 30, 2024, The Missouri Hemp Trade Association has filed a lawsuit in the Cole County Circuit Court seeking declaratory and injunctive relief that prevents the DHSS from designating these foods and beverage adulterated and implementing an embargo. The lawsuit argues that

these products are protected by state law because “industrial hemp” is defined separately from “marijuana” which is considered a controlled substance. This is in line with the 2018 Farm Bill, which removed hemp from the list of controlled substances regulated by the Drug Enforcement Agency. According to the plaintiffs, because the cannabinoids cited in the executive order are derived from cannabidiol (CBD) extracted from industrial hemp, they are commodities of industrial hemp and therefore not adulterated. They cite 196.070.02, RSMo, which states that “A food shall not be considered adulterated solely for containing industrial hemp, or an industrial hemp commodity or product.”

The DHSS has been actively enforcing the executive order, with news reports

stating that the agency inspected up to 74 establishments, and forced proprietors to destroy products that violate the embargo. According to a statement from the Missouri Hemp Trade Association, by compelling the embargo and destruction of the intoxicating cannabinoid products, “DHSS agents are putting themselves at significant risk of losing qualified immunity protections. Missouri law, under Revised Statutes 196.070.2, clearly states that food containing industrial hemp cannot be considered adulterated solely for containing hemp. By enforcing actions that violate this established statute, DHSS agents are actively breaking the law. Consequently, they not only violate legal protections but also open themselves to personal liability.”



## New Jersey Governor Signs Bill to Regulate Hemp-Derived Cannabinoids

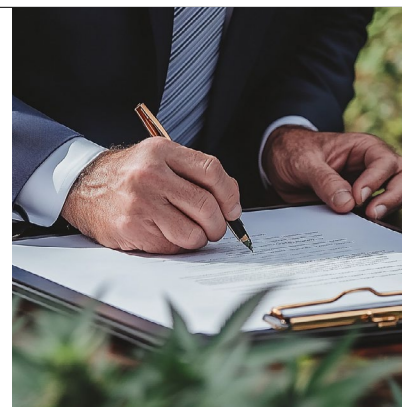
**ON SEPTEMBER 12, 2024**, New Jersey Governor Philip Murphy signed Senate Bill 3235, which regulates the production and sale of certain intoxicating hemp products. Immediately upon the governor's signature, the bill prohibits their sale to people under 21 years of age and, within 30 days of the governor's signature, prohibits the sale of these products from unauthorized sellers. Unauthorized sellers are defined as businesses that are not licensed and overseen by the Cannabis Regulatory Commission.

In particular, the bill addresses products containing forms of tetrahydrocannabinol (THC) such as delta-8-THC and delta-10-THC, which are intoxicating, but could potentially be considered a legal hemp product because of the low content of delta-9-THC.

Also released was a three-page statement from the governor, which outlines the new challenges created by two late amendments to the bill, namely, the need for regulations for businesses with licenses for selling and distributing alcohol to sell intoxicating hemp

beverages, and the changes to the definition of “intoxicating hemp product,” to add the phrase “in this State” after “any product cultivated, derived, or manufactured.” Despite the challenges presented, the statement explains, current state of the hemp product market necessitated immediate action.

“Over the past two and a half months, I and my team have heard from a number of stakeholders with differing views on this issue, as well as a number of legislators who supported the legislation,” the final paragraph of the governor's statement reads. “These discussions have convinced me that it is very unlikely that revisions to the bill would have the broad support necessary to move through the Legislature quickly. Unlike many issues, the status quo poses an immediate risk to health and safety, as these unregulated intoxicating hemp products are widely available to minors. Because the bill would address this present danger, I have concluded that the wiser course is to sign the bill now and commit to working with the Legislature



to address the technical issues and other challenges in separate legislation.”

The bill was sponsored by Senator M. Teresa Ruiz, and Senator Paul D. Moriarty.

“Today, New Jersey takes a major step to protect our children,” stated Senator Ruiz in a statement. “The lack of regulation of intoxicating hemp products and beverages has helped fuel a rise in cannabis-related hospitalizations and poses a threat to the well-being of our communities. Public health and safety should always be our top priority.”

Senator Moriarty also stated, “The regulation of Delta THC is a long-overdue outcome I have been working toward for several years now, and I am glad to see it finally come to fruition.”





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## South Carolina's Attorney General Issues Opinion on the Legality of Beverages Containing Hemp-Derived Cannabinoids

**A RECENT OPINION PUBLISHED** by South Carolina's Office of the Attorney General states that non-alcoholic beverages that contain hemp-derived tetrahydrocannabinol (THC) with concentrations of delta-9 THC of no more than 0.3% are legal in South Carolina. The opinion was in response to an inquiry from Representative G. Murrell Smith Jr., the state's Speaker of the House.

Smith wrote in a letter to the Attorney General's (AG) office that "Recently, South Carolina distributors have been request-

ed to provide hemp-infused beverages to various retailers in South Carolina... No statute, regulation, agency guidance or prior Attorney General Opinion I [sic] provides a clear answer as to whether these hemp-infused beverages that are manufactured, distributed, or sold in South Carolina are legal... Manufacturers and distributors in South Carolina need clear guidance."

The opinion from the AG's office explains that the passage of the 2018 Farm Bill removed hemp from the classification

of a controlled substance and was therefore made legal, so long as the concentration of THC remained at or below 0.3%. It does, however, state that the AG's office cannot make a "blanket" determination on the legality of this category of products without knowing whether each product meets this threshold of THC. This must be made on a case-by-case basis, says the opinion. Essentially, without a regulatory framework that ensures consistency across products, the AG cannot for sure know if every product marketed this way is legal.



## Missouri's Health Department Shifts Priorities in Enforcing the Governor's Executive Order Against Intoxicating Cannabinoids

**A LETTER FROM RICHARD MOORE**, deputy director and general counsel of the Missouri Department of Health and Senior Services (DHSS) indicates a change in enforcement priority for the DHSS in enforcing Governor Mike Parson's recently imposed ban on intoxicating hemp products. DHSS began enforcement of the governor's executive order at the beginning of September. Reports indicated that 74 retail establishments were inspected, and in multiple cases, business owners were forced to destroy inventory. The Missouri Hemp Trade Association (MHTA) also filed a lawsuit against the state in response to the executive order. The lawsuit cites 196.070.02, RSMo, which states that "A food shall not be considered adulterated solely for containing industrial hemp, or an industrial hemp commodity or product."

In the letter, Moore expresses agreement with 196.070.02, RSMo. He wrote, "In regard to psychoactive cannabis products, the Department will focus its efforts on the identification of 'misbranded' products as that term is defined in Section 196.075, RSMo. If the Department identifies any such misbranded products,

it will refer those products to the Missouri Attorney General's Office for potential enforcement under the State's Merchandising Practices Act, which, among other things, prohibits '[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in 2 connection with the sale or advertisement of any merchandise in trade or commerce[.]' To that end, the Department will aim to identify products that may violate the Merchandising Practices Act."

Moore states that cannabis products that have been embargoed will be released after 30 days. He explains that, "All psychoactive cannabis products that the Department has tagged as an embargoed product under Chapter 196, RSMo, since August 1, 2024, will be referred to the Attorney General's Office for evaluation of Missouri Merchandising Practices Act violations. The Department has no intention at this time to embargo additional psychoactive cannabis products as adulterated. Further, within 30 days

after referral to the Attorney General's Office, the Department will release all currently embargoed products and remove all embargo tags. Once embargo tags are removed, such product will not be subject to an embargo so long as there is no court order prohibiting its sale or ordering its destruction."

He also clarified that the executive order only pertains to intoxicating products. "Hemp or cannabidiol (CBD) products which are collected by extraction and have not been changed into a new substance, such as hemp protein powders, hemp milk, hemp flower, hemp teas or other drinks, CBD gummies, CBD drink additives, or foods with CBD, have not been embargoed to date," wrote Moore.

MHTA is advocating for the release of embargoed products sooner than 30 days. "Our legal team is working closely with DHSS and state officials to explore ways to expedite the process, ensuring that your products can be sold as soon as possible," wrote MHTA in a press release. "MHTA is committed to fighting for a quicker resolution, and we're exploring all legal avenues to make it happen."





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## California Emergency Hemp Regulations Now in Effect; U.S. Hemp Roundtable and Other Stakeholders File Lawsuit

**ON SEPTEMBER 23, 2024**, California's Secretary of State approved and filed emergency regulations proposed by the state's Department of Public Health on September 4, 2024. The regulations prohibit any detectable levels of THC from hemp products, limit the serving size of hemp products to five, and create a minimum age of 21 to purchase hemp-derived products. The purpose of the regulations, says California's Governor Newsom, is to protect consumers from intoxicating hemp products, but the regulations impact a wide swath of hemp-derived products including non-intoxicating extracts that contain cannabidiol. Many full spectrum hemp-derived extracts

contain 0.3% THC or less, which is the threshold allowed for hemp products set forth by the 2018 Farm Bill.

On September 24th, 2024, the U.S. Hemp Roundtable, a group of California hemp farmers, and businesses that include Cheech and Chong's, Juicetiva Inc., Blaze Life LLC, Boldt Runners Corporation, Lucky To Be Beverage Co., and Sunflora Inc., filed a lawsuit against the regulations.

"Gov. Newsom's misguided efforts to destroy a thriving hemp industry – one that he helped create in signing AB 45 three years ago – clearly violate state and federal law," said Jonathan Miller, U.S. Hemp Roundtable's general counsel, in a statement. "We are

confident that the courts will agree that the governor does not come close to demonstrating an 'emergency' exists, and the devastation that he would unleash on hemp farmers, small businesses and product consumers must be forestalled. We are hopeful that once relief is granted, the governor will finally meet with the hemp industry to appropriately address his stated mission: to develop a robust regulatory regime that promotes health and safety and keeps hemp products out of the hands of minors."

The U.S. Hemp Roundtable also intends to petition a temporary restraining order to prevent the regulation's enforcement until the close of the lawsuit.



## Senator Ron Wyden Introduces New Legislation for the Regulation of Hemp-Derived Cannabinoids

**SENATOR RON WYDEN (D-OREGON)** has introduced new legislation that would regulate the hemp-derived cannabinoid industry. The "Cannabinoid Safety and Regulation Act" would establish a regulatory regime for products that contain hemp cannabinoids. The bill would require manufacturers to register with the U.S. Food and Drug Administration (FDA) and test their products for potency, pesticides, heavy metals, chemical byproducts, and additives. FDA will be tasked with developing rules for the manufacture and testing of these products. Additionally, the bill would set a federal age limit of 21 on hemp-derived products, and prohibit the sale of synthetic cannabinoids. Labeling and packaging requirements would also be established to ensure that products are not designed to appeal to children, and accurately convey potency, risks of consumption, and lack of FDA review or approval.

"Just like the tobacco industry marketing cigarettes to young people, nobody should be slapping fun cartoons and glitzy candy wrapper packaging on cannabis products meant for adults," said Wyden, in a press

release. "A federal floor for regulation of hemp products is non-negotiable to ensure that consumers aren't put at risk by untested products of unknown origin. My legislation will ensure that adult consumers know what they're getting, and that hemp products are never sold or marketed to children."

The bill has the support of the hemp and cannabis industries. "The hemp industry is united behind a simple, common-sense proposition: Hemp products should be robustly regulated, not the subject of a misguided prohibition. Senator Wyden's critical legislation does just that: imposing strong health and safety standards for hemp products while ensuring that they are kept out of the hands of minors. Along with dozens of other hemp organizations, the U.S. Hemp Roundtable endorses this bill as we stand up and cheer for Senator Wyden's continued stewardship and leadership, and as we look forward to continuing to work closely with him as this bill progresses and transforms over the next several months," said Jonathan Miller, general counsel at U.S. Hemp Roundtable, in a press release.



"For too long, federal inaction has fostered an unregulated marketplace for hemp THC products, endangering the public and creating unfair competition for regulated cannabis businesses," added Aaron Smith, CEO at the National Cannabis Industry Association. "We look forward to working with Senator Wyden to pass the Cannabinoid Safety and Regulation Act because it solves this problem by implementing commonsense safeguards to ensure intoxicating hemp products are tested, properly labeled, and not made available to minors while creating a pathway for manufacturers to provide safe hemp products to adults through a regulated framework."

Previously, in 2021, Wyden introduced the "Hemp Access and Consumer Safety Act."

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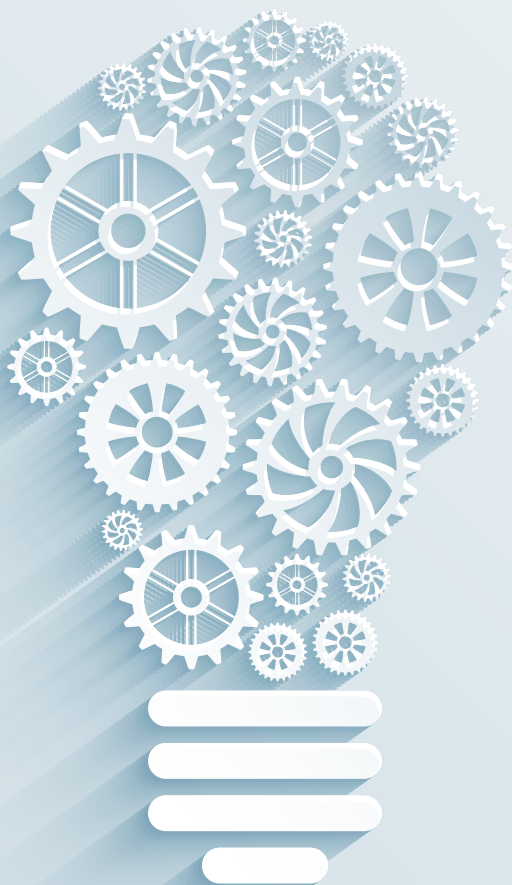
## An Update on the Hemp Regulatory Landscape

What does the current regulatory landscape look like and how will the 2024 Farm Bill change things for hemp as a supplement in the near future?

by **ERIN MCEVOY**, Assistant Editor

In December 2018, the U.S. hemp industry experienced a monumental change with the passing of the Agriculture Improvement Act of 2018, commonly referred to as the Farm Bill, which removed hemp from the list of federally controlled substances.<sup>1</sup> Subsequently, it enabled the cultivation, processing, and sale of hemp and hemp-derived products, with cannabidiol (CBD) being a significant cannabinoid in the new marketplace.<sup>1</sup> It also enabled transportation of legal products across state lines.<sup>2</sup>

Importantly, the 2018 Farm Bill provided this definition for hemp<sup>1</sup>: “The term ‘hemp’ means the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and



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all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” This definition differentiated hemp from marijuana and allowed it certain qualifications. For example, only hemp and hemp products are eligible to receive organic status from the U.S. Department of Agriculture.<sup>3</sup>

deputy commissioner of the Food and Drug Administration (FDA), released a statement regarding FDA’s position on regulatory oversight on CBD.<sup>5</sup> Essentially, FDA stated it would not regulate the CBD market, but rather work alongside Congress to create a regulatory framework. In the meantime, FDA stated it will “continue to take action against CBD and other cannabis-derived products to protect the public, in coordination with state regulatory

scary place to be for the cannabinoid industry. Only time will tell how it will all shake out.”

In a recent statement to *Nutritional Outlook*, Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN) explained, “More than five years ago, Congress purposefully removed hemp-derived CBD from the Controlled Substances List to jumpstart a market, yet FDA refuses to recognize that directive. While FDA delays, a sizable market has grown for CBD, and lack of a regulatory scheme punishes the companies making legitimate product from the bad actors. FDA owes it to consumers to follow the direction from Congress and create a legal pathway to market for non-intoxicating hemp-derived CBD.”

In the midst of this situation, there has been legislation created that would enable the regulation of hemp-derived CBD products through already-existing legal pathways. For example, in July 2023, Senators Ron Wyden, Rand Paul, Jeff Merkley, and Representative Earl Blumenauer, re-introduced S. 2451, the Hemp Access and Consumer Safety Act, intending to provide consumer safety by regulating hemp-derived CBD products by the FDA.<sup>8</sup> Currently, the Federal Food, Drug, and Cosmetic Act prohibits substances studied or approved as a drug to enter the market as a dietary supplement; however, FDA could establish exemptions.<sup>9</sup> At its core, S. 2451 intended: “To allow for hemp-derived cannabidiol and hemp-derived cannabidiol containing substances in dietary supplements and food.” As a result, these products would be used in food, beverages, and supplements; would comply with federal regulations on manufacturing; and would be properly labeled.<sup>9</sup> The legislation gained support from over a dozen organizations including American Herbal Products Association (AHPA) and the U.S. Hemp Roundtable, however it was not passed.<sup>10</sup>

## “The patchwork of different state laws introduces additional challenges to the hemp industry to comply with ever-changing regulations and in establishing efficient interstate commerce.

— Erin Dillon, American Herbal Products Association

Passed every five years by Congress, the legislation in the Farm Bill governs agricultural and other programs in the country. In 2023, through the Further Continuing Appropriations and Other Extensions Act, 2024, programs in the Farm Bill were allowed to continue until September 30, 2024.<sup>4</sup> Even though in many ways it seems like little has changed since last year, the implications of the 2024 Farm Bill, including currently proposed amendments, are expected to be wide-reaching for the hemp industry.

### A Standstill with Past Legislation

The years since the 2018 Farm Bill have resulted in frustration across the industry from a lack of definitive regulatory action regarding hemp-derived cannabinoids. In January 2023, Dr. Janet Woodcock, the then principal

partners, when appropriate.” That has mostly taken the form of sending warning letters to companies making illegal and unsubstantiated health claims with their CBD products.<sup>6</sup>

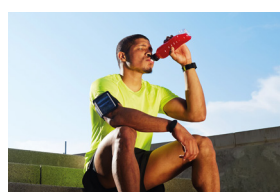
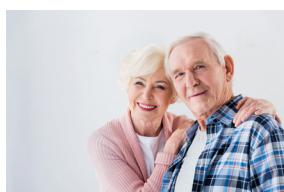
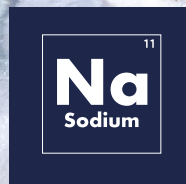
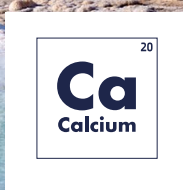
Kim Stuck, founder and CEO of Allay Consulting, covered FDA’s announcement in 2023 and offered suggestions for companies to still remain compliant with their cannabis products.<sup>7</sup> “We suggest following FDA’s established current good manufacturing practices (cGMP) for food and dietary supplements, get cGMP certification from an accredited third-party company, follow tetrahydrocannabinol (THC) potency restrictions, be cautious when making health claims for hemp products, make friends with the state or local authority who has jurisdiction over your establishment, and work with a third-party compliance firm. Someday we will look back on this and laugh, but right now it feels like a





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On September 25, 2024, Senator Wyden introduced the Cannabis Safety and Regulation Act (CSRA), which was co-sponsored by Senator Merkley.<sup>11</sup> With this legislation, FDA would be required to recall or ban unsafe hemp products, set the minimum age for purchasing products to 21, require testing for safe production and clean manufacturing, and require truth in labeling. As Wyden explained, this bill intends to create a “federal regulatory floor” for hemp products.

Jonathan Miller, U.S. Hemp Roundtable’s general counsel, noted in the press release, “The hemp industry is united behind a simple, common-sense proposition: Hemp products should be robustly regulat-

to face significant challenges. Since the Farm Bill, states have resorted to creating their own regulations for hemp-derived cannabinoids. For example, some states have created licensing requirements for manufacturers and retailers, testing for contaminants, and labeling and traceability.<sup>12</sup>

Comprehensive restrictions on certain hemp-derived cannabinoids are becoming more common as products containing intoxicating, synthetic cannabinoids, such as delta-8 tetrahydrocannabinol (delta-8-THC), emerged through a perceived loophole in the Farm Bill’s definition of hemp. Major concerns have arisen because of the availability of these products, including to minors, in retail locations other than licensed dispensaries.

and consumers, including medical cannabis patients, as it would severely reduce the types of products available to consumers. The introduction of legislation restricting hemp products this year mirrored similar legislation in 2023, namely, California’s AB 420, which also sought to limit THC levels in hemp products.<sup>15</sup>

In an interview with *Nutritional Outlook*, Jane Wilson, American Herbal Products Association’s (AHPA) director of program development, explained, “Various limitations have been introduced at the state level (ranging from no detectable THC allowed in a hemp cannabinoid product to varying limits on the amount of THC in a serving size/product package of a hemp cannabinoid product). The patchwork of different state laws introduces additional challenges to the hemp industry to comply with ever-changing regulations and in establishing efficient interstate commerce. The variation in the limits also indicate a potential lack of a scientific basis in determining these limits and whether the limits are related to specific health and safety concerns.”

AHPA also highlighted its guidance policy (introduced in 2021 and revised in December 2023) stating that delta-8-THC and other synthesized and artificial cannabinoids should be sold through channels for adult use products.<sup>16</sup> Furthermore, the policy, “discourages labeling or marketing as ‘hemp’ any products that consist of or contain any amount of synthesized cannabinoids for consumption by any route, and encourages identification in labeling and marketing of any synthetic cannabinoid ingredient by an accurate common or usual name; and further, AHPA strongly discourages the marketing of products for consumption by any route that consist of or contain any amount of artificial cannabinoids.”

Jonathan Miller explained in a recent interview with *Nutritional Outlook*: “There are intoxicating cannabinoids

**“If the Mary Miller amendment stays in the Farm Bill, it would devastate the industry – 99 to 95% of products would be declared illegal...”**

— Jonathan Miller, U.S. Hemp Roundtable

ed, not the subject of a misguided prohibition.” He also further explained in an interview with *Nutritional Outlook*, “a Wyden bill, if it passes, would have a tremendous impact. It would hopefully bring all of these different regulatory regimes together, and particularly on an issue like labeling, to have some federal standards, as opposed to having to have 50 different state standards.”

### **New Challenges Introduced by Intoxicating Hemp-Derived Cannabinoids**

In addition, regulation of hemp and hemp-derived products has continued

In a recent example of state legislation limiting products containing intoxicating hemp-derived cannabinoids, in September 2024, California Governor Gavin Newsom introduced emergency regulations regarding hemp products.<sup>13</sup> This proposal comes on the heels of California’s Assembly Bill 2223. The legislation, proposed earlier this year, would have limited the amount of THC in hemp products, but it failed to pass the Senate.<sup>14</sup> While both the emergency regulations and AB 2223 reportedly were in response to intoxicating cannabinoids harming minors, both received criticism for their predicted negative effect on hemp products, retailers,

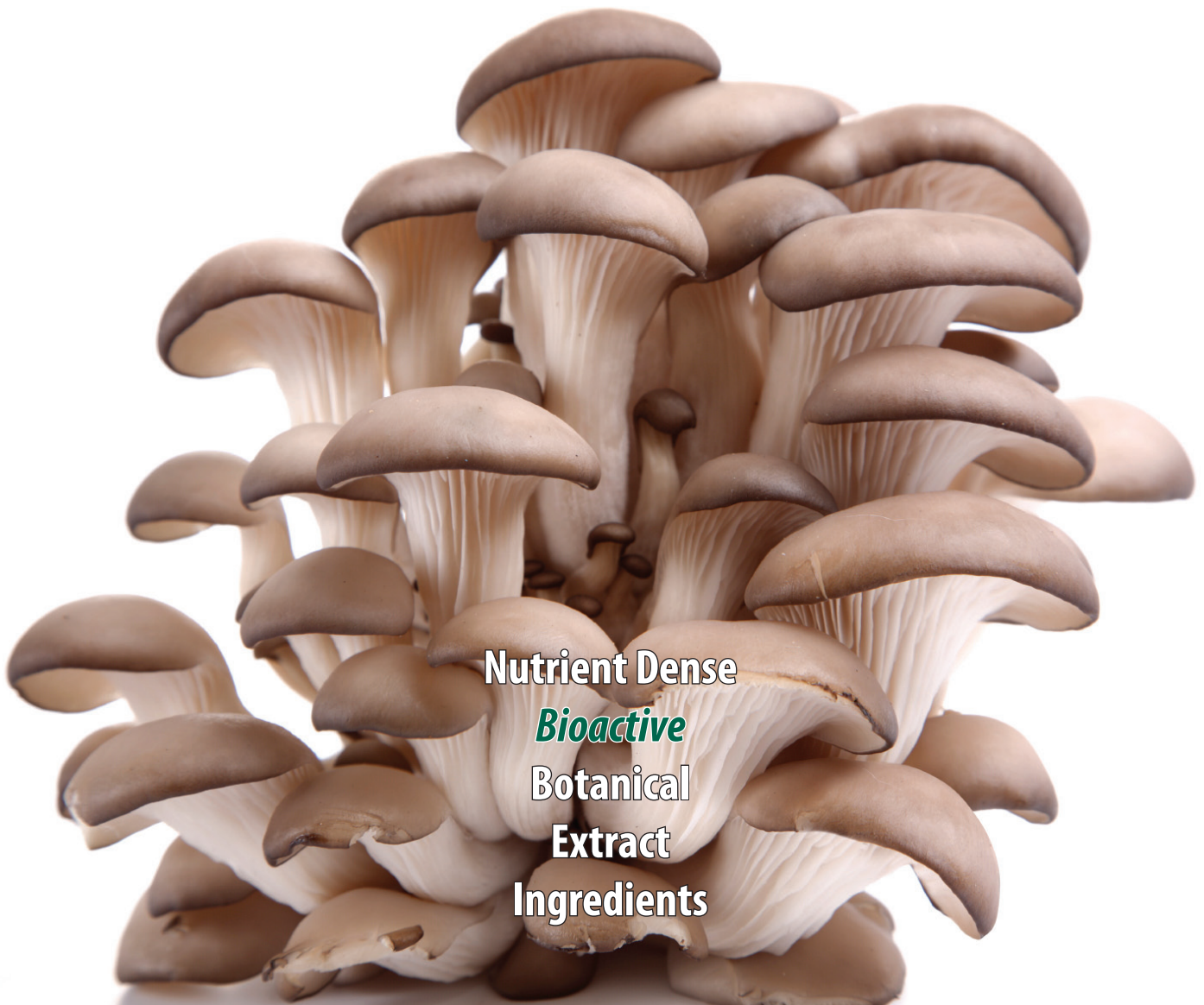




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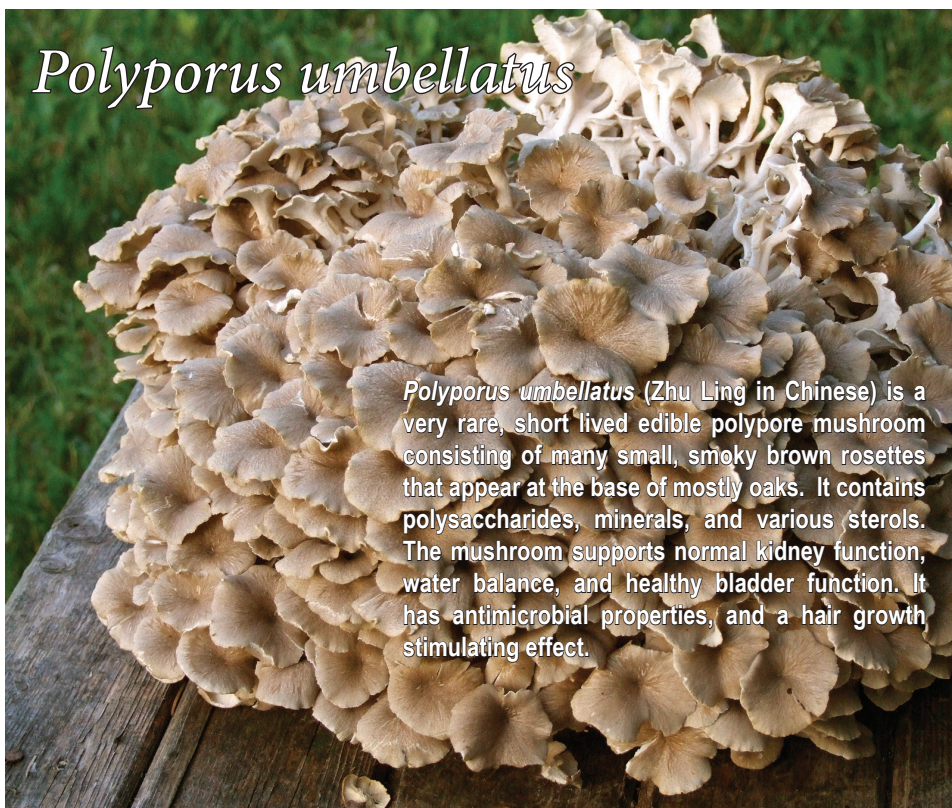
Cordyceps Cs-4 extract is cultivated from the fungal strain *Paecilomyces hepiali* derived from the species *Cordyceps sinensis*. The original strain is an endoparasitic fungus that grows out of the body of a caterpillar (pictured). It contains essential vitamins and minerals and is rich in powerful polysaccharides. It supports a healthy immune system, energy levels, positive mood, libido, healthy aging, kidney and liver health, and improved lung function.

## Lion's Mane

**Lion's Mane mushroom** (*Hericium erinaceus*) grows in a single large clump of dangling spines on the side of hardwood trees. Medically, it helps support normal cholesterol and lipid levels, cognitive health and mood, and immune health. Human studies show a beneficial effect for cognitive health and mood in aging populations. Active constituents in Lion's Mane have been shown to stimulate nerve growth factor associated with repair and rejuvenation of the brain and nervous system in animal experiments.



## Polyporus umbellatus



*Polyporus umbellatus* (Zhu Ling in Chinese) is a very rare, short lived edible polypore mushroom consisting of many small, smoky brown rosettes that appear at the base of mostly oaks. It contains polysaccharides, minerals, and various sterols. The mushroom supports normal kidney function, water balance, and healthy bladder function. It has antimicrobial properties, and a hair growth stimulating effect.

**Agaricus blazei murrill (ABM)**, also known as Himematsutake, is native to Brazil and popular in Japan. Its fruiting bodies appear as button caps singly or in clusters in leaf litter. It is a very good source of nutritious vitamins and minerals. It is also rich in complex polysaccharides and sterols. The mushroom supports normal cell function and normal seasonal histamine levels, and boosts immune function.

## Agaricus ABM





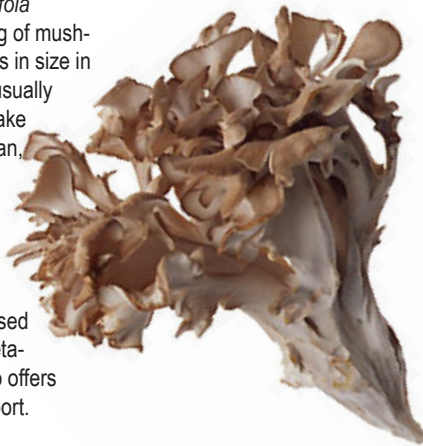
**Enokitake** or Enoki (*Flamulina velutipes*) is an edible mushroom popular in gourmet Japanese restaurants. It grows at the base of the Chinese Hackberry tree. It is an anti-aging mushroom with blood pressure and cholesterol lowering effects that has also been used effectively for gastroenteric ulcers. It has significant anti-tumor effects. Enokitake can also be used to support healthy liver function and healthy cognitive function.



Enokitake

## Maitake

**Maitake mushroom** (*Grifola frondosa*) is known as the “king of mushrooms” as it grows up to 100lbs in size in large clusters of leafy ruffles, usually at the base of oak trees. Maitake is a culinary mushroom in Japan, but is also used in Traditional Chinese Medicine as a remedy to help support normal intestinal comfort, healthy weight management, normal blood sugar levels, and increased exercise output. Containing beta-glucan polysaccharides, it also offers powerful immune system support.



Turkey Tail

### Turkey Tail mushroom

(*Trametes versicolor*, syn. *Coriolus versicolor*) is a polypore mushroom with flat caps that grow in concentric zones of varying color on decomposing wood. Rich in polysaccharides and sterols that support immunity; prostate, liver and breast cellular health; and normal inflammation response. The mushroom stimulates SOD activity and liver detoxification; inhibits fat formation and helps reduce body fat, and reduces influenza viral replication.



Tremella

**Tremella mushroom** Tremella comes from the Latin word for “to tremble”, which appropriately captures its gelatinous qualities. There are over 100 species of this “jelly fungus” recognized worldwide. *Tremella fuciformis* or Snow Fungus, is generally flavorless, but provides support for immunity, cardiovascular and cognitive health, normal blood sugar, and normal cell growth. It also soothes chronic cough and dry throat, and helps manage inflammation.



## Reishi

**Reishi mushroom** (*Ganoderma lucidum*) is a medicinal mushroom that has symbolized great health and longevity throughout thousands of years of Chinese history. It is used in Chinese herbal medicine for supporting a calm state of mind, energy, and normal cell function. Scientific studies show that it helps promote a healthy immune response, normal liver function, and a healthy seasonal histamine response.

## *Poria cocos*

***Poria cocos*** grows underground as a sclerotium, which is a compact mass of hardened mycelium. It helps promote healthy kidney and bladder function, and digestive and stomach health. *Poria cocos* is also known to support calmness and healthy sleep by reducing anxiety, tension, and fatigue. It stimulates healthy brain function, reducing memory loss. As with many other mushrooms, it helps with a healthy immune response, and supports a normal inflammation response with topical use.







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and there are ones that are marketed to kids and are copycats, and the latter are a real problem for the industry. We encourage states and the federal government to crack down on them, but in terms of just natural intoxicating cannabinoids, they are the lifeblood of the industry, and they need to be kept away from minors. We support strong regulation. They need to be manufactured properly, but they should continue to be sold or retailed to adults under appropriate regulations.”

### The Mary Miller Amendment

A recent and significant complication to future hemp regulation is the proposed amendment to the draft version of the House of Representative’s Farm Bill, known as the “Mary Miller amendment,” which was submitted by Illinois Representative Mary Miller and approved in May 2024.<sup>17</sup> In a statement, Miller explained that the amendment intended to keep THC products packaged like candy away

from minors.<sup>18</sup> However, the amendment “would significantly impact cannabinoid products,” explained AHPA. “This amendment is intended to close the ‘delta-8 THC loophole’ in the 2018 Farm Bill by excluding from the definition of hemp any cannabinoids that are not capable of being produced by the plant and those capable of being produced, but that were synthesized or manufactured outside of the plant. It also excludes quantifiable amounts of THC/THCA and any other cannabinoids that have ‘similar effects.’”

Jonathan Miller further explained the consequences to the amendment. “If the Mary Miller amendment stays in the Farm Bill, it would devastate the industry—99 to 95% of products would be declared illegal, and there would be no real industry to speak of, if it does pass.”

As of the time of publication, Congress failed to meet the deadline for passing a Farm Bill in 2024.

### Looking Toward the Future

With legislation and regulation seemingly pulling the industry in several directions at once, it may seem like it’s being pulled apart and under threat of disappearing. However, when envisioning the long-term future of hemp regulation in the U.S., a few main ideals consistently appear as necessary for the industry to thrive. As Jonathan Miller explained, the U.S. Hemp Roundtable would ideally like to see hemp-derived cannabinoids “appropriately regulated, robustly regulated, that they’re kept out of the hands of kids, that they use good manufacturing practices, truth in labeling, and that they are offered safely and legally to adults across the country.”

These ideals should be a common denominator among all stakeholders in the hemp industry. Hopefully, they can be used as a guiding set of principles to find common ground for legislation. ■

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# To Spore or Not to Spore ...

The health benefits and limitations of  
spore-forming probiotics.

by **JOY CHOQUETTE**, Contributing Writer

When it comes to probiotics, most health-minded Americans likely have the basics down. Probiotics are thought to be beneficial for gut health and potentially improving the state of one's microbiome. They are also considered important for immune health. This was proven during the COVID-19 pandemic, when rates of probiotic use increased.<sup>1</sup>

People's interest in probiotics isn't fading. In fact, the CAGR for probiotics in general is forecast to rise 7.9% between 2020 and 2027, and from \$44.48 billion to \$94.48 billion during that time period.<sup>1</sup> But when it comes to spore-forming probiotics, there may be more to learn.

## The Effectiveness of Spore-forming Probiotics

Spore-forming probiotics, as their name implies, produce spores which are thought to improve their effectiveness in the body. Reshma Rath, vice president of operations at Specialty Enzymes & Probiotics (Chino, CA), states that two of the greatest benefits of this type of probiotic are survivability and stability. Spore-formers, Rath states, create a protective endosphere, allowing them to survive in varying environments in greater numbers. That includes every part of the process from storage, processing, and the transport to an individual's stomach acid.

"Spore-formers are resistant to heat, light, pH variability and other environmental stressors, allowing them to survive industrial processing and remain shelf-stable without the need for refrigeration," notes Rath. For manufacturers, she points out, this means fewer resources used and greater options in the viability of the product. "For consumers, it means they are getting more value and benefits from their supplements," says Rath.



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## Spore-forming Probiotics: The Health Benefits

Shaheen Majeed is global CEO and managing director of Sabinsa (East Windsor, NJ) and states that the health benefits of choosing spore-forming probiotics influence the balance of the gut microbiota. One of the company's products, LactoSpore is a spore-forming probiotic which is in powder form upon production. "In this powder form, the culture is dormant and stable with a three-year shelf-life at room temperature," says Majeed. "The culture survives the harsh stomach conditions upon consumption as a food ingredient. When it reaches the intestine, where the conditions are suitable, it enters the germination stage, where it produces valuable metabolites."

In addition, there are other benefits to spore-forming probiotics. Senior vice president of business development and marketing of Bio-Cat (Troy, VA), Mark G. Walin, says that these powerful probiotics may further help the digestive system. "They can produce digestive enzymes to aid in the breakdown of food components such as proteins, fats, and carbs supporting gut health," says Walin. Additionally, "They can produce antimicrobial compounds that can help mitigate the growth of pathogenic bacteria."

Walin states that clinical studies support the health benefits of these special probiotics. "*Bacillus subtilis* has been shown in numerous studies to decrease gastrointestinal symptoms and can assist with protein digestion," notes Walin. "Additionally, there is growing evidence that spores such as *Heyndrickxia coagulans* (formerly *Bacillus coagulans*) helps reduce the severity of IBS [irritable bowel syndrome] symptoms."<sup>2</sup>

## Limitations to Spore-forming Probiotics

While spore-forming probiotics

“  
[Spore-forming probiotics] can produce digestive enzymes to aid in the breakdown of food components such as proteins, fats, and carbs supporting gut health.

—Mark G. Walin, Bio-Cat

may offer a lot of powerful benefits, it's important to consider their limitations as well. Not all products are created equal and quality is an important place to look first. Rath explains, "Choosing high-quality, research-backed, proven strains is essential to ensure formulators know what they're putting in their products and marketing to their consumers. Working with experts in the field can help formulators select the best strains to target their desired results."

Walin notes that no matter how versatile a probiotic is—and spore-forming probiotics are very versatile—there are other things that must be taken into consideration. "There can be limitations to every probiotic because not every strain will have the same effects in every person," Walin states. "Current diet, lifestyle, and health factors can all play a role in how a person responds to any given probiotic."

With more interest in probiotics now than ever before, the world of spore-forming probiotics specifically is one that has a bright and seemingly healthy future. **N**

**Joy Choquette** writes from Vermont.

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# The “Joys” of Menopause

From hot flashes to moodswings, menopause is rough on women, and they are actively seeking out solutions.

by **JUDY BLATMAN**, *Contributing Writer*

In the U.S. alone, more than 2 million women every year reach menopause. That translates to about 6,000 women daily. If you count 81 years as the average life expectancy, as the Mayo Health System does, women spend more than one-third of their lives in the three stages of menopause: perimenopause, menopause, and post-menopause.<sup>1</sup>

Perimenopause—when a woman's ovaries start producing less estrogen and progesterone leading to fewer and irregular monthly periods—often starts to affect women in their early to mid-40s; however, some women show signs as early as their 30s.

After 12 months of a woman going without having her period, she is officially in menopause and can no longer become pregnant. This is followed by post-menopause, which lasts the remainder of a woman's life.

Symptoms tend to be fewer and more mild during this period, but for some, they remain a significant challenge to their health and well-being.

## Menopause is Not a Monolithic Experience

As we hear (too often these days) from political pollsters, demographic groups are not monoliths when it comes to voting; the same can be said about women going through the change of life. While they may experience similar symptoms during all three stages of menopause, the manifestation of those symptoms can vary from woman to woman in intensity, effects, and duration.

There is some good news, however, that goes beyond those physically exhausting, emotionally draining, and psychologically challenging symptoms. For example, some experts say the way our society looks at this time in a woman's life is changing for the better.





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Komal Baldwa, founder of India-based Waleria Healthtech, believes that “the perception of menopause has significantly evolved in recent years, but there is still a long way to go in addressing the gaps that remain from past neglect of women’s health. This evolution can be seen across various groups, although the pace and depth of change differ.”

The shift among consumers is remarkable, she says. “Women are becoming more empowered,

Herein lies an opportunity for the women’s health category for ingredients and dietary supplements, particularly for those companies committed to providing scientifically backed solutions.

Monsalve points out that “Women, and those who care for them, are eager for solutions that can bolster their health and allow them to live life to the fullest. As Kerry research has shown that 8 out of 10 consumers throughout the world have consumed sup-

As Monsalve explains, “Before, during, and after menopause are all times of great change in a woman’s body, and therefore life. Naturally, women have become more interested in a proactive approach to wellbeing with a focus on prevention, as 75% stated that they are adopting a long-term health plan.”

She suggests that by taking steps to prioritize wellbeing, women can set themselves up for success not just at their annual checkups, but



**77% of women remain hesitant to use hormone therapy despite experiencing menopause-related symptoms.**

— Komal Baldwa, Waleria Healthtech

seeking knowledge, and advocating for their health. Online forums and support groups are fostering self-education, and women are turning to alternative therapies and solutions.”

Izaskun Monsalve, PhD, global marketing manager for women’s and infant health, proactive health at Kerry Group (Tralee, Ireland), concurs. “In recent decades,” she says, “society has made significant strides in empowering and emboldening women to seek out the lives they want for themselves.”

However, Monsalve adds, “While women should be able to navigate life’s cycles with as much ease and clarity possible, there’s still work to be done.”

The demand for more comprehensive and accessible menopause care is growing, states Baldwa, and it’s “women who are driving this momentum, leading the charge and shifting the narrative around menopause.”

plements in the last year, it is the most direct way to provide positive health benefits to the masses.”

Further, Baldwa notes that “studies show that 77% of women remain hesitant to use hormone therapy despite experiencing menopause-related symptoms. With an increasing number of women seeking natural, non-pharmaceutical alternatives, the industry must develop effective, safe, and validated products.”

For example, she adds that “many women prefer non-hormonal options for symptom management, and ingredients like black cohosh, Shatavari, and omega-3s offer natural alternatives that support holistic health.”

## A More Proactive Approach to Health

It seems like common sense—the healthier you are throughout your life, the healthier you will be as you go through the change of life.

year-round. “Early attention to the immune system, eyes, brain, and hormonal health through supplements and diet are easily accessible steps that can alleviate health issues later in life,” says Monsalve.

“At Kerry,” she says, “we encourage and help women to take ownership of their own menopause journey and make informed decisions that can have long-lasting positive effects on their health, and we provide products which can help through this important life-stage. Taking charge and adopting proactive practices for all around health, like incorporating supplements into daily routines, can ease these years that have traditionally been painful for women.”

## Symptoms and Science

Some of the more common and most complained about symptoms that occur during menopause are hot flashes, night sweats, fatigue, anxiety, and insomnia.



## “Taking charge and adopting proactive practices for all around health...can ease these years that have traditionally been painful to women.”

— Izaskun Monsalve, PhD, Kerry Group



Fortunately, there are a number of natural, branded ingredients available in dietary supplement products for women to combat these symptoms.

One ingredient for relief from common menopausal symptoms is Libifem, a branded fenugreek extract from Gencor Pacific (Austin, TX). Maggie McNamara, vice president of global marketing for Gencor, pointed to a published study, funded by Gencor Pacific (who also supplied the investi-

gational products), in which the standardized *T. foenum-graecum* de-husked seed showed what she said were “excellent outcomes to support [the reduction of] hot flashes and night sweats.”<sup>2</sup>

The double-blind, randomized, placebo-controlled clinical trial was conducted in a cohort of healthy women, aged 40-65, either perimenopausal or menopausal, who were experiencing symptoms such as hot flashes, night sweats and other related symptoms.

Among the findings, the study authors noted that “over the study period, a gradual significant reduction (approximately 50%) in total flushes was observed in the active treatment group ( $p < 0.001$ ),” leading them to suggest that the proprietary treatment ingredient was “an effective treatment for reducing vasomotor symptoms and associated menopausal symptoms in otherwise healthy women.”<sup>2</sup>

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branded ingredient, Luprenol, with 8-Prenylnaringenin (8-PN), is a scientifically backed phytoestrogen ingredient that has been demonstrated to safely combat these symptoms, offering relief through menopause, says Monsalve. She explains that “in a clinical study on the active ingredients in Luprenol, specifically 8-PN, one of the strongest known phytoestrogens, women who took the solution experienced a 40% reduction in hot flashes and a 32% improvement in symptoms of nervousness, fatigue, and excessive sweating.”<sup>3,4</sup>

This past April, Waleria announced the results of a new study investigating its *aspurū*s Shatavari root extract for the management of menopausal symptoms and regulation of hypothalamic-pituitary-ovarian (HPO) axis.

The 8-week, prospective, randomized, double-blind, multi-center, placebo-controlled study enrolled 70 participants split between a test group receiving *aspurū*s Shatavari root extract and a placebo group. The participants were pre- and post-menopausal women between the ages of 40-65 years old who were experiencing menopausal symptoms such as hot flashes, night sweats, anxiety, fatigue, and mood swings. The primary outcome measure was the total score of Utian Quality of Life (UQoL).<sup>5</sup>

The study results revealed reductions in the test group compared to placebo in symptoms such as hot flashes, night sweats, anxiety, fatigue, and insomnia. Regarding the UQoL scores, improvements were significant in the test group indicating a tangible enhancement in overall well-being. When compared to

placebo, the test group saw an 85% reduction in hot flashes in as few as 4 weeks, a 90% reduction in night sweats in 8 weeks, and 60% greater reduction of reported sleeplessness.<sup>5</sup>

“The findings demonstrate compelling evidence of the efficacy of *aspurū*s in supporting menopausal symptoms and enhancing overall quality of life,” said Danielle Greenberg, research consultant at Waleria Health, in a press release. “The significant reductions in hot flashes and night sweats coupled with the notable improvements in Utian Quality of Life scores show the potential of *aspurū*s to offer meaningful relief for women experiencing menopausal transition.”<sup>6</sup>

## Bone Health is Foundational During Menopause

Most often when we think about peri- and menopausal symptoms, it's the ones that give the “ick factor”—the night sweats, the hot flashes, the mood swings, the vaginal dryness—that are most often associated with the hormonal changes.

However, there are other symptoms that can be serious too. For instance, strong bones are foundational to a healthy body, and it's no secret that aging makes us more prone to bone loss and bone breakage. According to Jennifer Gu, PhD, vice president, research and development at AIDP (City of Industry, CA), “It is well-known that menopausal women lose bone density

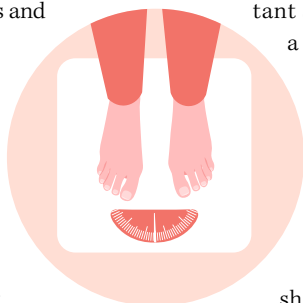
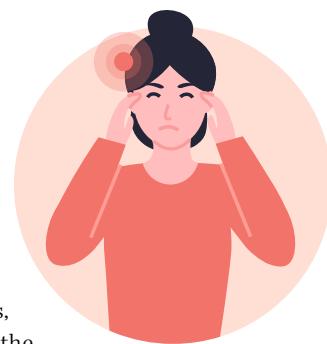
at an accelerated rate. In fact, bone fractures are a major concern for aging women.”

One of AIDP's foundational branded ingredients, KoAct, has been on the market for around 15 years, supported by clinical research and three U.S. patents for its unique composition as well as its application in improving bone mineral density and bone strength, according to Gu. She explains that the formulation “goes beyond calcium supplementation and other general bone supplements by providing calcium and bone collagen at the same time.”

In the ingredient's earlier years, AIDP, Inc. funded the first long term-clinical trial to directly compare the effects of calcium collagen-chelated products (KoAct) to calcium and vitamin D in postmenopausal females. The 12-month, randomized controlled trial studied 39 postmenopausal women divided into two groups, one group taking calcium-collagen chelate, the other, a capsule mix of calcium and vitamin D.<sup>7,8,9</sup>

The study was led by Bahram H. Arjmandi, PhD, RDN, an internationally recognized expert in nutritional interventions for bone health and other health conditions. The investigation found that “the group taking the calcium-collagen chelate, saw a loss of 1.23% in bone mineral density, while the control group saw a 3.75% loss.”<sup>8</sup>

Further, Dr. Arjmandi commented at the time “that supplementation with KoAct may provide





protection against bone loss and increased bone turnover for which supplementation of calcium and vitamin D alone could not achieve." The study was published in the *Journal of Medicinal Food*.<sup>9</sup>

### Hair, Skin and Nails Still Matter in Menopause

If it seems vanity-based only, consider that thinning hair, dry skin, and brittle nails can add to diminished confidence and emotional distress for menopausal women already dealing with other issues that may challenge their feelings of femininity.

Earlier this year, AIDP announced results from a randomized, double-blind, placebo-controlled study published in the *HealthMed Journal* on the effects of Keragen-IV oral supplementation on hair and skin. Although the study was not specifically conducted in menopausal

women, the age range of 45-60 may give women in the change of life some hope.<sup>10,11</sup>

The 60-day trial studied 65 females with healthy skin and damaged or stressed hair, receiving either the keratin-based formulation (Keragen-IV), or placebo. At the end of the trial, the Keragen-IV group experienced significant improvements in reduced hair loss (43%) as well as a 17.61% improvement in the birefringence of the hair cortex, compared to placebo. These results suggest that the functional ingredient that shares homology with keratin naturally present in human hair may increase the structural integrity of the hair cortex in as little as 60 days.<sup>10,11</sup>

As for skin health, there were also some positive results. The treatment group saw a significant 10% increase in comparison to the placebo group in gross skin elas-

ticity after 60 days. In addition, there were improvements in skin barrier function with oral Keragen-IV, after 30 days, measured by 12.5% lower levels of trans epidermal water loss, a non-statistically significant improvement when compared to placebo.<sup>10,11</sup>

AIDP's Gu served as one of the principal investigators in the trial. She stated, in part, that "this study verifies Keragen-IV's role in hair anchoring which is a concern for many women experiencing hair loss due to hormonal changes or stress."<sup>10</sup>

### Putting Women at the Forefront of Research

Waleria's Baldwa is energized by what she is seeing from the research community where, she says, "institutions like the University of Melbourne are leading the way with innovative approaches,

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such as focusing on preventive strategies and understanding menopause as a natural life stage rather than a medical condition to be treated.”

What's more, she says that this signals a shift towards a more proactive and holistic approach. She points to the University of Leeds which she states “is known

how ingredients are metabolized can be significant. For example, hormonal fluctuations, differences in body composition, and variations in metabolism can all play pivotal roles in the efficacy of natural products.”

She advocates that “this targeted approach is critical and necessary to understand better how

can also drive medical research into underexplored areas like cardiovascular, mental, and bone health for women.

She adds that it is also “our responsibility [as an industry] to maintain that trust [sought] out by women, by investing in new research and collaborating with healthcare providers. This ensures



**“[A] targeted approach is critical and necessary to understand better how functional ingredients can safely and effectively benefit female physiology.”**

— Jennifer Gu, PhD, AIDP Inc.

for its research into menopause, particularly in workplace support and the socio-economic impacts of menopause. Their work often highlights the importance of accommodating menopausal women in the workforce.”

Gencor has long been an advocate for studying ingredients in female (and male) populations and McNamara says that “one of the most pressing areas for advancement in the industry is the focus on female-only populations in clinical research.” That’s because, as she explains, “the biological differences between males and females are well-documented, and

functional ingredients can safely and effectively benefit female physiology. It also enables brands to develop supplements tailored to women’s unique needs rather than repackaging ingredients previously only studied in male physiology.”

Baldwa also finds it crucial for women to continue to speak out, especially openly discussing their menopausal symptoms and the need for relief. In that way, she says that “women can normalize menopause as a natural life stage, encouraging others to share their experiences, seek help, and prioritize their health.”

This is the kind of personalized advocacy that Baldwa believes

that our products complement other treatments and contribute to more integrated care.”

Kerry’s Monsalve, too, believes that “it’s imperative that the industry as a whole fully recognize menopause as a global health issue, guiding women through options to optimize their own health.” ■

#### Judy Blatman Communications

LLC specializes in writing for industry publications and clients, strategic counsel, and media training. Ms. Blatman spent 16 years as SVP, Communications, Council for Responsible Nutrition.

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# Pregnancy Over 35

How can we better support preparation and recovery in a population of new (older) moms?

by **AMANDA FRICK, ND, LAC**, *Contributing Writer*

The average maternal age for women in the United States has steadily risen over the past fifty years. According to the U.S. Census Bureau, the average age of mothers reached a record high of 30 years in 2019. For comparison, in 1970, the average maternal age of U.S. women was 24.6 years.

There are many reasons why women are waiting to have children at a later age. Many of these involve education and job opportunities, greater accessibility to reproductive technologies, and the ability to complete certain milestones before starting family planning. Today, 20% of women in the U.S. give birth to their first child after age 35.

The good news is there are multiple benefits for moms when starting a family later, including cognitive and longevity benefits.

The downside is that pregnancies after age 35, or what healthcare practitioners call “advanced maternal age,” come with a higher risk of complications to both mom and baby. Some of these risks include gestational diabetes, preterm birth, increased chromosomal abnormalities and other birth defects, and miscarriage. Risk factors extend to recovery post-birth as well.

The most significant contributing factors to these risks are likely related to ovarian aging, resulting in decreased quality of eggs later in life, and a general increased risk for chronic disease that occurs with age.

Despite these risks, there are various nutritional factors which may help to reduce the risks of pregnancy in women over the age of 35. During pregnancy we know that there is an





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increased need for essential nutrients like iron, vitamin D, and calcium making nutrition and supplementation increasingly important. Taking a high-quality prenatal vitamin that includes iron, folate, choline, and other nutrients to support a healthy pregnancy at any age is essential.



## Folate

We've known for decades that adequate folate intake prior to conception is important to prevent neural tube defects.<sup>1</sup> In addition, emerging data suggests that it may also reduce risk for other fetal structural abnormalities,<sup>2</sup> including heart defects,<sup>3</sup> and may help to protect against early delivery, a risk factor with advanced maternal age. Common food sources of folate include dark leafy greens, beans, and peas.



## DHA

We know that omega-3 is important for fetal brain development for preg-

nant women of all ages.<sup>4</sup> Importantly, there is also some evidence that supplementing with omega-3 fatty acids may help to reduce risks commonly associated with pregnancy after 35, like preterm delivery.<sup>4</sup> Food sources of DHA include fish, shellfish, and algae.



## CoQ10

Levels of this important antioxidant and energy producing nutrient decrease with age and may also be associated with decreased egg quality and fertility rates. Studies show that supplementing with CoQ10 prior to natural and assisted fertility efforts can help support egg and embryo quality by protecting eggs from oxidative damage.<sup>5</sup> Some food sources for CoQ10 include organ meats, fatty fish, and soy.



## Inositol

Supporting insulin sensitivity is important for everyone, but may

become increasingly important in advanced maternal age, where there is an increased risk for gestational diabetes. Supplementing with inositol can help to support pregnancy rates, which is a challenge with women over 35.<sup>6</sup> Increasing consumption of fruits, veggies, grains, and nuts can help boost choline intake.

Recovering from pregnancy may prove to be a challenge for older women as well.

While age alone may not factor into increased risks, women over 35 may be more prone to other factors that make them more susceptible to post-pregnancy complications like postpartum depression and slow physical recovery. These risks increase dramatically over age 40, and in mothers with multiple births.

In addition to following the nutrient recommendations, keeping up with protein intake, omega-3s, and a quality prenatal or multivitamin with iron and quality B vitamins can help to support recovery time and reduce risk for postpartum depression.

Understanding how women can be best supported and recover from pregnancy later in life is critical for mom and baby as advanced maternal age will likely continue to be more common in the years to come. **N**

**Dr. Amanda Frick, ND, LAc** is the vice president of medical affairs at Thorne. She leverages her expertise in naturopathic medicine to bring a personalized, science-backed approach to the health and wellness and nutritional supplements space.

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# Plant-Based Potential

Protein content food continues to increase, creating new challenges for plant-based protein formulators.

by **SEBASTIAN KRAWIEC**, *Managing Editor*

The plant-based protein category continues to evolve and grow as formulators find creative ways to develop protein-rich, great tasting products that can compete with dairy-based proteins like whey or casein. The category has come a long way since soy dominated the market. Since then, the variety of plant-based protein sources has increased quite a bit, providing formulators greater flexibility, and consumers more choice. Soy continues to be an important option for formulators, because it is a complete protein. However, as an allergen, not everyone can rely on soy as a protein source. Pea protein has emerged another excellent option for plant-based protein, being nearly a complete protein and more versatile so that it can be used across multiple applications.

Depending on the application, blending proteins is a popular strategy to develop a product that offers the right protein and amino acid profile in addition to taste and mouth-feel. “We know that 41% of plant protein powders only use one protein source, 39% use two, and 16% use three, and I think a lot of that is due to trying to get [as close] to that optimum protein score that they can,” explains Melissa Machen, principal technical account manager at Cargill (Minneapolis, MN). “So, certainly not only in powders but in ready-to-drink applications and bar applications, we see blends. Pea protein and rice protein are complementary. They have complementary amino acids. So where one is lacking the other one [makes up for the deficit], and really, it’s a pretty high ratio of pea [protein] to a lower ratio of rice [protein] to get to that level.”

The quality of the protein matters. This is measured by the protein digestibility corrected amino acid score (PDCAAS). Amino acids are necessary for the digestion of protein in the body.





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Limitations in amino acids reduce the body's ability to absorb the protein. This is quite important for athletes and people who do not consume meat or dairy. However, even people who get protein from multiple sources actively shop for high protein content claims. "Across the board, I think consumers are becoming more aware of protein, what total protein means, what complete protein means," says Machen. Therefore, the total grams of protein are important to consumers, as well as the percent daily value. Interestingly, the percent daily value is based on the complete protein score, meaning that the PDCAAS determines what percent daily value can be put on the nutrition facts panel. Cargill, for example, uses a PDCAAS calculator.

"When we're formulating these different products, we're looking to see how much protein are we getting, how much of it is complete out of this formulation, do we need to add some rice [protein], do we need to add another protein source to complement what we have with pea," explains Machen. Another way she has seen brands manipulate the amino acid profile is by adding individual amino acids to the formula to compensate for what may be lacking.

"It becomes a huge challenge because especially in ready-to-drink type products where they're going through a high heat process, it becomes a challenge to make sure that [the amino acids] are in the product in the finished state," says Machen.

In addition to protein quality, the taste and texture is also paramount. However, chasing higher protein content with plant-based proteins does not always lend itself to the most pleasing finished product. Different formats have different standards. Powders, for example, are not held to the same standards of taste and texture as an RTD or bar format. "When we think about a ready-to-mix powder versus a

ready-to-drink beverage, formulations are very different...[With] powders, they're ready to mix, people shake it in their protein shaker, they drink it pretty quickly or they're like shaking it every time they drink. So, in that case, solubility isn't as critical as in those ready-to-drink products where it's going through a UHT system. Maybe it's going through like aseptic filling it's going through much more severe processing, so that's where we look at different proteins."

The biggest challenge in the marketplace, says Machen, is that protein levels continue to increase, particularly in beverages, and the higher the protein content goes, the harder it is to use plant-based proteins. On average, says Machen, RTD beverages will contain 20 grams of protein, and many are pushing 25 grams. With its Puris 2.0 pea protein, for example, Cargill is able to achieve over 20 grams of protein, but the higher you push the protein content, the greater the susceptibility of certain process challenges, like solubility, and issues with protein stability. The use of hydrocolloids, starches, and lecithin ingredients can also help with production in high protein systems, she explains.

"[When it comes to beverages] people think about chalkiness...People want it to be a very smooth, creamy texture, almost like fluid milk or something like that," says Machen. "So, that's probably one thing that comes up quite often where advances with our Puris pea protein products really have given us that opportunity to have more solubility, to not be as chalky, to not be as astringent and to reduce some of those plant-based beanie or bitter notes that you have traditionally seen within the plant protein space."

Pushing the protein content of a bar or extruded snack is even more difficult to achieve because of moisture migration. Extruded snacks and bars

have a lot more components in a low moisture system compared to beverages, says Machen. "So, if you think about a bar, a lot of the components of a bar is an extruded protein or it's a [protein] powder...So, you're going to have carbohydrates, and you're going to have fiber in there as well as the protein. You may also have a little bit of fat, just to give it some lubricity in the mouth," she explains. Flavoring is another thing to consider in a low moisture format like a bar or extruded snack. While a beverage can use a small amount of natural flavoring to get the desired flavor profile, low moisture formats may have additional flavoring inclusion such as nuts or dried fruit. Understanding how proteins mix with these other ingredients is crucial.

"That protein, no matter what it is, likes to absorb water," says Machen. Therefore, ensuring that these products maintain their desired texture throughout shelf life is paramount.

According to the International Food Information Council's 2024 Food & Health Survey, protein consumption is on the rise. In 2024, 71% of respondents said they are trying to consume more protein, compared to 59% in 2022, and 67% in 2023. In that same survey, 54% of respondents stated that they are following a specific eating style or diet, of which the highest cited diet was high protein. Vegetarian, plant-based and vegan diets amounted to 8% of respondents, and 5% were flexitarian. All these intersect to create demand for plant-protein powders or plant-protein-fortified foods and beverages. The challenge for plant-based protein formulators is developing products that appeal to a wide range of consumers that aren't limited to just plant-based products. Luckily, openness to alternative protein sources and advances in food technology are helping formulators push the limits of plant-based protein and deliver great products. ■



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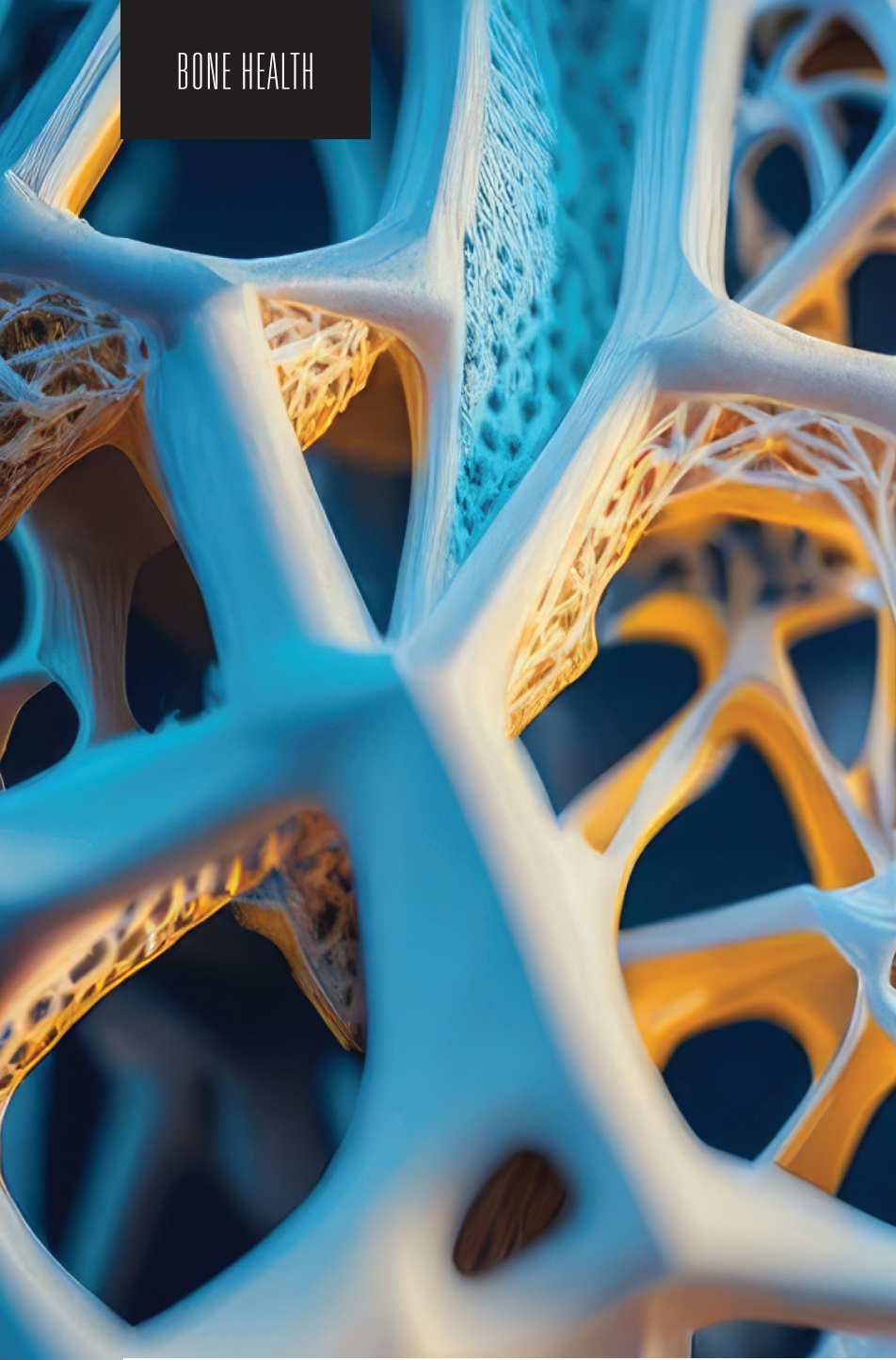
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# Healthy Bones *via the Gut*

A look at the science demonstrating the gut microbiome's impact on bone health.

by **SEBASTIAN KRAWIEC**, Managing Editor

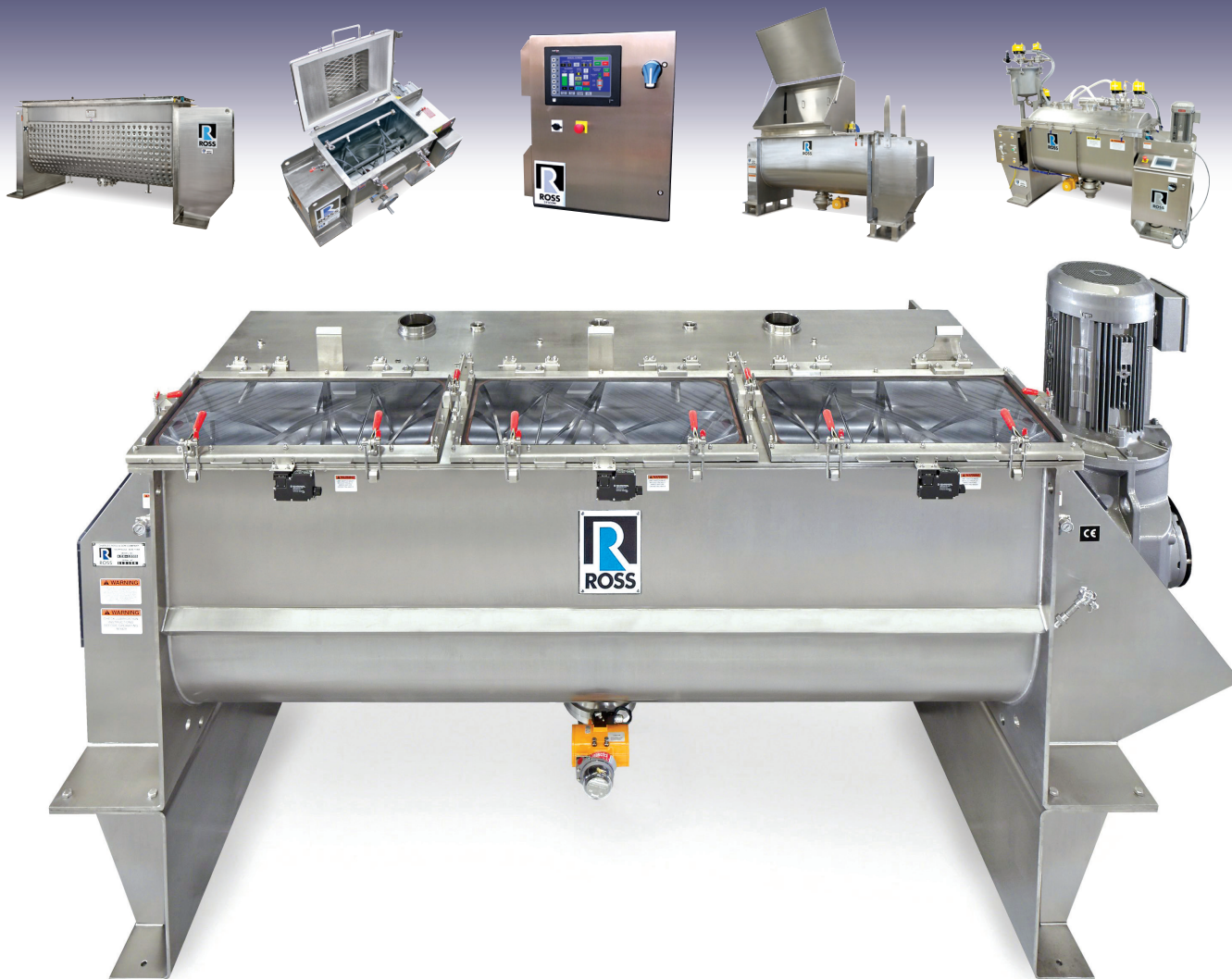
A growing body of scientific literature has been drawing connections between the health of the gut microbiome and other physiological systems, including brain, skin, and heart health. Emerging research is also pointing to the microbiome's impact on bone health.

Bones are both structural and serve as a reservoir for minerals such as calcium and phosphorous. These minerals give the bones their “hardness,” while proteins such as collagen give bones “softness,” allowing them to sustain some mechanical pressure without breaking easily.<sup>1</sup> Cells called osteoblasts are responsible for bone formation by producing collagen, which serve as a scaffold for calcium and phosphorous to deposit into. Osteoclasts are cells that resorb bone, adhering to the bone to dissolve and release mineral deposits. In a healthy system, there is a constant interaction between osteoblasts and osteoclasts. However, when this homeostasis is disrupted, conditions such as osteopenia, characterized by lower-than-normal bone mineral density, or even osteoporosis can occur. This is typically caused by the over activation of osteoclasts, degrading more bone than osteoblasts can rebuild.

Bone mass naturally decreases with age, but bone health is influenced by a number of factors, including nutrition and physical activity. Another potential factor impacting bone mass, researchers are finding, is the microbial composition of the gastrointestinal tract. A dysbiotic gut microbiome has been associated with bone diseases such as osteoporosis. Research has shown that people with osteoporosis have a significantly higher microbiome diversity (in this case, not a good thing), characterized by an abundance of *Firmicutes*. Animal studies have shown that the administration of antibiotics to deplete the gut microbiome was found to restore bone mass.<sup>2</sup>

That said, a healthy functioning gut microbiome does beneficially impact





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bone health. For example, the microbiome is a source of vitamin K<sub>2</sub>, required for osteocalcin function and bone formation through the stimulation of osteoblasts. A different animal study also found that a decrease in vitamin K<sub>2</sub> levels following antibiotic-induced microbiome depletion was associated with reduced osteocalcin and bone strength in mice.<sup>3</sup> Additionally, while antibiotics may reduce the population of detrimental bacteria, they do the same for beneficial bacteria, such as butyrate producing bacteria, which is a short chain fatty acid (SCFA) associated with bone formation.<sup>4</sup> For example, antibiotics can cause the depletion of Bacteroidetes. The reduced abundance of this bacteria is also associated with inflammatory bowel diseases and type 1 diabetes, which are populations that experience excessive bone loss.<sup>4</sup>

## Mechanisms

The gut microbiome can influence bone remodeling both directly and indirectly. For example, the release of microbial metabolites such as SCFAs is one direct mechanism by which the microbiome influences bone remodeling, while indirectly, the gut microbiome can regulate bone remodeling through its interaction with immune cells such as T helper cells 17 or T regulatory cells, as well as hormones such as estrogen.<sup>4</sup>

SCFAs are produced through microbial fermentation of non-digestible dietary fibers. The production of some SCFAs is limited to specific bacterial strains. For example, researchers have linked the production of the SCFA propionate to *Akkermansia muciniphila*,

*Eubacterium dolichum*, *Ruminococcus bromii* (*R. bromii*), *Bacteroides eggerthii*, *Bacteroides fragilis*, and *Veillonella parvula*. Butyrate producing bacteria belong to specific bacterial families, namely Clostridiaceae, Eubacteriaceae, Lachnospiraceae, and Ruminococcaceae. Propionate, butyrate, and acetate are SCFAs that have been demonstrated to increase bone mass through inhibiting the production of osteoclasts through a variety of distinct mechanisms.<sup>4</sup>

The gut interacts with the immune system via the intestinal epithelium. Inflammation in the gut can impact the secretion of immune cells. For example, it can result in the production of inflammatory immune phenotypes such as T-helper 17 cells, which produce the proinflammatory cytokines interleukin-17 (IL-17).<sup>1</sup> The increase of T-helper 17 cells and IL-17 in bone marrow has been shown to promote bone degradation by stimulating the differentiation of osteoclasts in the bone marrow. On the other hand, T regulatory cells can have a beneficial impact on bone health because of their immunosuppressive functions. Evidence shows that certain microbes can regulate bone remodeling by changing the balance between T-helper 17 cells and T regulatory cells. T regulatory cells work by inhibiting osteoclastogenesis and promoting bone formation through the secretion of anti-inflammatory cytokines, such as IL-4, IL-10, and transforming growth factor-beta.

## Human Research

A recently published study using two large human cohorts identified a potential link between specific bacteria and

bone density/strength.<sup>5</sup> In the study, researchers investigated the association between the gut microbiome and scans of radius and tibia of two large human cohorts using high resolution peripheral quantitative computed tomography. The cohorts were the Framingham Heart Study (FHS) with 1227 participants between the ages of 32 and 89, and the Osteoporosis in Men Study (MrOS), with 836 participants between the ages of 78 and 98. Results showed that there were 37 microbial genera in the FHS and 4 in the MrOS cohort whose abundance was associated with skeletal health measures.

Meta-analysis of the taxa-bone association found that greater abundance of *Akkermansia* and *Clostridiales bacterium DTU089* were associated with lower radius volumetric bone mineral density (vBMD) and tibia cortical vBMD, respectively, while a higher abundance of *Lachnospiraceae NK4A136* group, and *Faecalibacterium* was associated with greater tibia cortical vBMD. The researchers also observed that there was a great number of bacteria that were negatively associated with bone density but positively associated with bone size, which they speculate could indicate that certain microbes help promote the growth of bones at the expense of bone density as a person ages. While the study finds some interesting patterns, more research is necessary to draw any conclusions about the relationship between specific microbes and bone health. As the body of research grows, the relationship between the gut microbiome and bone health offers exciting new possibilities for product development. ■

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# Frivolous Class Action Lawsuits Plague Omega-3 Industry

The Global Organization for EPA and DHA Omega-3s' vice president of regulatory and scientific affairs talks about recent class actions and why they are without merit.

by **HARRY RICE, PHD**, Contributing Writer

Throughout my 20+ year career, I've seen a lot of regulatory changes, some bad, some good; however, the uptick in the last five plus years of class action suits is disheartening, particularly given the frivolousness of the complaints. I am particularly appalled at the rash of omega-3-related class action lawsuits with a range of allegations, from false and misleading labeling to challenges on claims associated with cardiovascular health. Too many omega-3 companies have been the victims of these lawsuits, the majority of which are filed in what are often considered the class action hotbed states: California and New York.

In 2021 and 2022, six class action complaints were filed against omega-3 companies alleging that the products being sold — omega-3 fatty acid ethyl esters, also known as omega-3 concentrates — were not fish oils and therefore should not be labelled as fish oil. The plaintiffs claimed that they had been deceived and had they known that the products were concentrated omega-3s, they wouldn't have purchased them. The reality is that most consumers don't know the difference between EPA/DHA attached to a triglyceride versus EPA/DHA attached to an ethyl ester, but it doesn't really matter as long as you are taking your supplement on a regular basis. The bottom line is that these consumers sought to purchase an EPA/DHA-rich oil and that's exactly what they got.

Of the six lawsuits, five have been dismissed, while the sixth against Mimi's Rock (owner of the Dr. Tobias brand) remains active, at least for now. On August 26, 2024, the defendant's motion to dismiss was denied in part and granted in part. Among the dismissed claims was the plaintiff's allegation associated with labelling ethyl esters as fish oil because of a failure to prove that a reasonable consumer was likely to be deceived. While this particular claim was dismissed, it was done so with the ability to be amended and on September 23, 2024, a third amended complaint was filed. The defendant's response is due by October 21, 2024.



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After a quiet 2023 with no significant class action complaint filings against omega-3 companies, 2024 started off with a bang. Thus far, four class action lawsuits have been filed against companies selling fish oils, all alleging some variation of using false and misleading cardiovascular claims (i.e. 'supports heart health'). In addition, at least three demand letters have been sent to omega-3 companies regarding their use of 'supports heart health.'

range of outcomes, and a large percentage of those are on cardiovascular health. Of course, EPA/DHA isn't a panacea, but when it comes to heart health, the preponderance of the scientific evidence supports multiple heart health benefits of EPA/DHA.

Four years ago, GOED's vice president of data science, Aldo Bernasconi, and several colleagues, including a practicing cardiologist, coauthored a peer-reviewed publi-

myocardial infarction (MI) (35%), MI (13%), coronary heart disease (CHD) events (10%) and CHD mortality (9%). In addition, there was a 5% non-statistically significant reduction in cardiovascular disease (CVD) events. Based on the results, the authors concluded that "supplementation with EPA and DHA is an effective lifestyle strategy for CVD prevention."

Less than a year later, the meta-analysis was updated and published with results from STRENGTH (Outcomes Study to Assess STatin Residual Risk Reduction With EpaNova in HIGH CV Risk Patients With Hypertriglyceridemia) and OMEMI (Omega-3 Fatty acids in Elderly with Myocardial Infarction), two subsequent, not to mention controversial, trials published after the publication of the aforementioned meta-analysis. With the addition of the two trials, the analysis included 42 studies and 149,359 participants. While the new results change the meta-analysis estimates slightly for CVD events (4% non-statistically significant reduction) and CHD events (9% statistically significant reduction), estimates for all other outcomes remained unchanged as did the overall conclusions – "supplementation with EPA and DHA is an effective lifestyle strategy for CVD prevention."

The data don't lie. Fish oil helps support a healthy heart. ■

**While there are many benefits associated with fish oil, there's no more substantiated benefit than for heart health.**

Only time will tell if any of these companies will end up having a class action complaint filed against them. As far as the four active cases are concerned, they are in the early stages, so there's little to report.

From a scientific perspective, these four cases are undeniably without merit. Fish oil supports heart health. While there are many benefits associated with fish oil, there's no more substantiated benefit than for heart health. There are now over 5,000 clinical (i.e. conducted in humans) trials on the effects of EPA/DHA on a wide

cation of their rigorous meta-analysis linking an increase in omega-3 intake to positive cardiovascular outcomes. The meta-analysis of 40 studies and 135,267 participants included data from ASCEND (A Study of Cardiovascular Events in Diabetics), VITAL (Vitamin D and Omega-3 Trial) and REDUCE-IT (Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial) and found that higher omega-3 dosages are correlated with statistically significant increases in risk reduction for a variety of cardiovascular outcomes, including: fatal

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# Making the Most of Outsourcing

From strategic outsourcing to turnkey solutions, contract manufacturers are helping supplement manufacturers meet growing demands and innovate.

by **SEBASTIAN KRAWIEC**, Managing Editor

Outsourcing can be an important way for manufacturers to grow and adapt. While many manufacturers may take pride in their manufacturing capabilities, processes, and qualities, everyone has their limitations, and contract manufacturers can help fill these gaps.

According to a 2023 survey conducted by *Contract Pharma*, in partnership with *Nutraceuticals World*, 28% of respondents cited a lack of resources and expertise, and 26% cited the ability to focus on other business priorities as reasons for outsourcing.<sup>1</sup> This is echoed by Mike Young, chief commercial officer of Vitaquest International (West Caldwell, NJ), who says that the full turnkey outsourcing the company provides, “allows [brands] to focus on their marketing, selling, artwork, and distribution strategies.”

According to a survey from the U.S. Department of Health and Human Services (DHHS), published in April of 2023 (based on data from 2017-March 2020), 34.4% of children and adolescents and 58.5% of adults take dietary supplements.<sup>2</sup> A separate survey from The Council for Responsible Nutrition (CRN; Washington, D.C.) found that 74% of U.S. adults take dietary supplements, of which 55% consider themselves regular users.<sup>3</sup> The CRN survey also found that 92% of respondents agreed with the statement that “Dietary supplements are essential for maintaining health.” Clearly, there’s a high interest in dietary supplements for their various health benefits, and therefore an appetite to manufacture and market products to what amounts to a majority of adult consumers. This means competition.

“One out of every three products that Vitaquest produces is new to the world,” says Young, highlighting just how much growth and innovation the industry is seeing. These new products may come from emerging brands who are not equipped to manufacture finished products or well-established brands who want to explore new dosage formats they may not have



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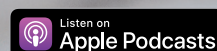
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## [Outsourcing] allows [brands] to focus on their marketing, selling, artwork, and distribution strategies.

## OUTSOURCING

experience making, or simply don't have the capacity to produce. Sometimes well-established brands need to outsource just so they can meet demand for popular product SKUs.

"Many key brands, even if they manufacture for themselves, they will strategically outsource," explains Young. "They could do that for a multitude of reasons. It could be they need an expedited launch for a new SKU, could be that they're just scaling so fast, they need some extra capacity or bandwidth by request."

Strategic outsourcing, like all outsourcing, requires a great deal of communication between the contract manufacturer and the client. "The more information they can share with us if we're going to strategically outsource an existing SKU; down to the vendor and raw material, it's all very critical," says Young.

A good example of the importance of working closely with a contract manufacturer is flavoring. "To match flavor, for example, on a powder product or a chewable tablet, it's critical to work very closely with the customer to get as much information as possible to match that flavor."

Outsourcing is very common, and a great way to do business, however, it's important actively monitor product quality and consistency. For example, NOW recently issued a voluntary recall<sup>4</sup> following testing performed by Consumer Labs found that its phosphatidyl serine 300 mg softgels did not meet label claims. According to the brand, its specifications demand an 8% overage for its products to ensure label claims over shelf life. NOW eventually determined that a contract manufacturer it was using had difficulty blending lecithin and achieving uniformity in the products. This situation posed no health risk, but demonstrated how despite certain safeguards, things can still go awry. As a result, NOW has added more safeguards to its QA protocols, particularly for products made by third party manufacturers.

Good contract manufacturers will also have their own protocols in place that ensure quality and consistency.

For example, Vitaquest's Young explains that, "Each formula that we put through our system goes through a rigorous quality process. We certify each supplier and certify each ingredient, through our in-house lab."

Reputable companies that offer turnkey solutions have a reliable supply of vetted ingredients, which is invaluable to brands just entering the space. Each contract manufacturer may offer expertise in particular areas of manufacturing. Gummy manufacturing, for example, is very difficult and without the right expertise, results in a subpar, ineffective products. Vitaquest, for its part, is highly capable in powders, recently acquiring a facility that allows them to do fluid bed agglomeration in-house. This process makes powders easier to work with, such as improving dispersion in liquids.

At the end of the day, contract manufacturers are helping to drive innovation and product development in the dietary supplement space. **■**

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# CBN, CBG, *And* More: The Big Picture About Minor Cannabinoids

A look at hemp's minor cannabinoids and their potential health benefits.

by **SCOTT MAZZA**, *Contributing Writer*

**T**here's much more to cannabis and cannabinoids than the famous three-letter compounds of THC and CBD. Beyond these two, regarded for their respective psychoactive and therapeutic applications, there's a wider world of cannabinoids.

From CBN to CBG and THCA, there are more than 100 cannabinoids in the plant with different psychoactive and non-psychoactive components. Indeed, each cannabinoid counts different attributes, with research only beginning to scratch the surface of how we can leverage specific cannabinoids for specific conditions.

Let's look into the big picture about minor cannabinoids – what we know, what they do, and what's next.

## **Why Cannabis Is More Than THC and CBD**

While THC and CBD dominate discussions due to their abundance and attributes, the cannabis plant offers a far richer tapestry of compounds.<sup>1</sup> Over 120 minor cannabinoids exist alongside these well-known compounds, each with unique pharmacological profiles. These lesser-known plant properties interact with various bodily systems, including cannabinoid receptors, transient receptor potential channels, and peroxisome proliferator-activated receptors.


The potential of these minor cannabinoids extends beyond recreational use with emerging research suggesting therapeutic applications for conditions such as neuropathic pain, neurodegener-

ative diseases, skin disorders, and even cancer. As our understanding grows, so does the promise of harnessing these compounds for targeted medical and life-style treatments.

## **What Research Tells Us So Far**

Despite CBD and THC taking most of the investigative attention, early research into minor cannabinoids offers some exciting results. For example, let's start with CBN. Studies suggest<sup>2</sup> that CBN can improve sleep quality with evidence pointing to its ability to increase the duration of non-REM sleep and reduce nighttime wakefulness. Additionally, CBN shows promise<sup>3</sup> in pain management, particularly when used in conjunction with





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CBD<sup>4</sup>, offering a potential avenue for relief without the side effects associated with pain medications. Further, researchers observe<sup>5</sup> anti-inflammatory properties in CBN, as it interacts with specific receptors and pathways to reduce inflammation.

And this is just one cannabinoid. Other highlight findings include CBG suppressing cancer cell growth,<sup>6</sup> THCA exhibiting neuroprotective properties,<sup>7</sup> and various minor cannabinoids – including THCV, CBC, CBG and CBDV – showing promise<sup>6</sup> against

on the body, including analgesic, anti-inflammatory, and neuroprotective actions.

### Why This Matters and the Big Promises of Minor Cannabinoids

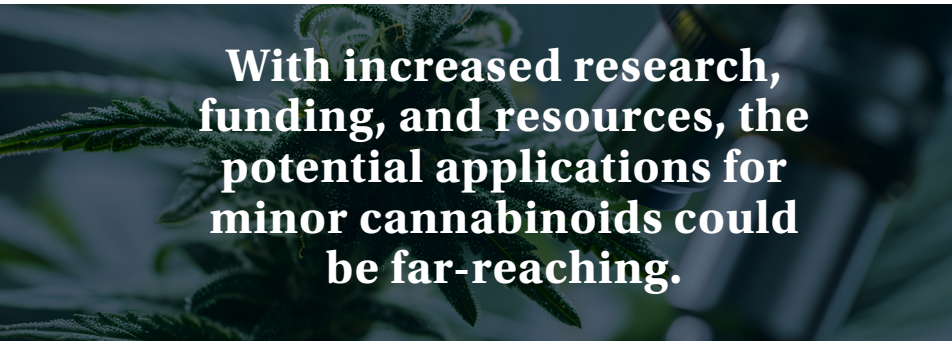
The cannabis plant is indeed much more than the sum of its parts, offering a complex array of compounds with likely medical and nutritional applications. Let's hope regulators see the potential here and cut red tape for minor cannabinoids. Unfortunately,

labeling. At the same time, however, blanket bans aren't the solution.

Of course, psychoactive compounds usually attract more attention than their non-psychoactive cousins, and there are still great medical and scientific gains to be made by researching and applying the latter. Nonetheless, this is still a regulatory landscape that's positioned against more liberal cannabis policy and it remains to be seen what happens next. Let's look forward to the upcoming federal election and improving public perception to move the needle toward more cannabis and cannabinoid rights.

Regardless, early research is giving us an exciting peek into minor cannabinoids and medical possibilities. By advocating for sensible policies, supporting rigorous research, and maintaining an open dialogue between scientists, regulators, and the public, we can unlock the full potential of these remarkable compounds. This includes things like developing new nutritional supplements, enhancing personalized well-being plans, and complementing existing therapies with minor cannabinoids. The journey may be complex, but the potential rewards in human health make it a path worth pursuing. **■**

**Scott Mazza** is the cofounder and COO of Vitality CBD (Buffalo, NY). Hailing from a background in finance, Scott is well versed in the benefits of hemp and is passionate about providing people with a natural alternative to the pharmaceuticals.



**With increased research, funding, and resources, the potential applications for minor cannabinoids could be far-reaching.**

skin disorders. These early findings are just the beginning. With increased research, funding, and resources, the potential applications for minor cannabinoids could be far-reaching.

Finally, it's also worth mentioning the emerging evidence to support the "entourage effect"<sup>8</sup>, the theory in which the entirety of the cannabis plant and its cannabinoids, terpenes, and flavonoids work in concert to amplify positive effects. Researchers report<sup>9</sup> each of the compounds "play a substantial role in interacting and collaborating" to exert various effects

what we've seen so far isn't promising. Cannabis' most well-known secondary cannabinoid – Delta-8 THC<sup>10</sup> – is in regulators' crosshairs with bans in almost 20 states.

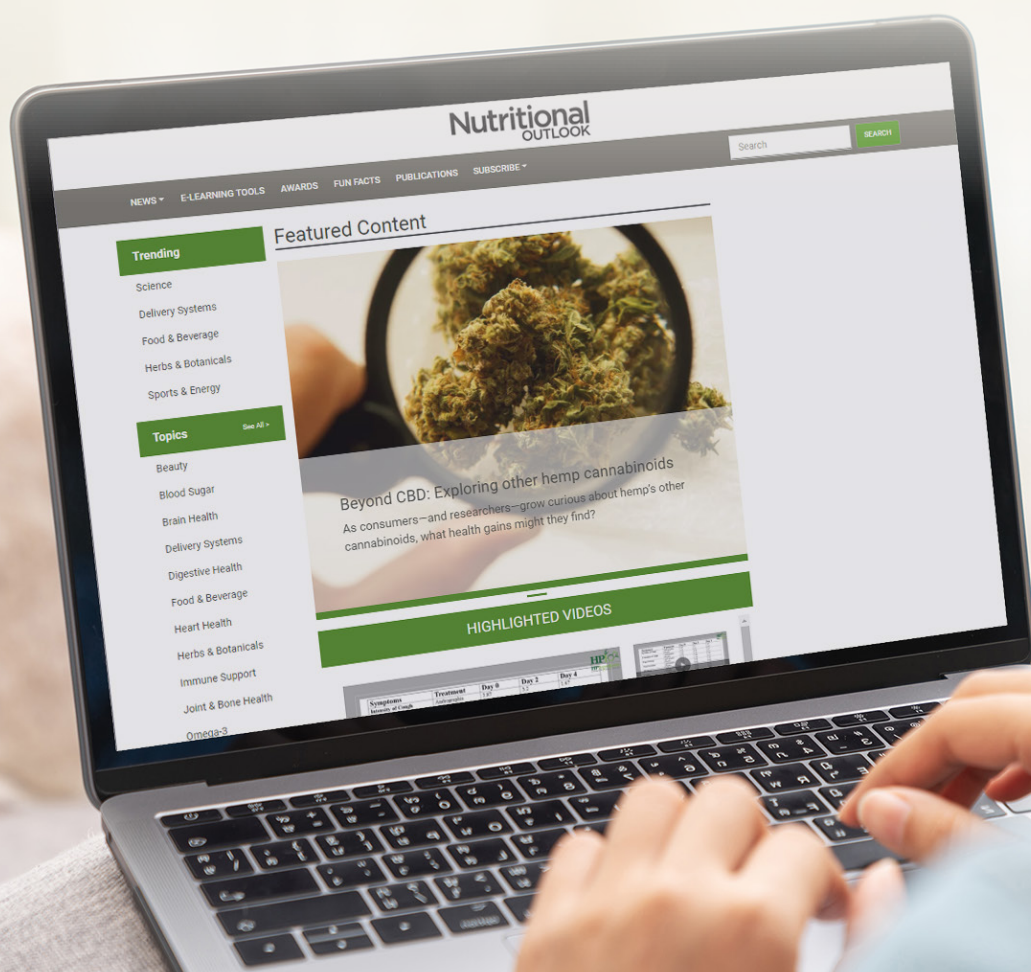
It's worth noting that regulators are (rightly) concerned about how some producers in this space synthesize the compound with harsh chemical processes or fail to test their products. For consumers, as with the wider landscape in CBD, a lack of government oversight demands caution, with best practices to check for third-party lab certifications, marketplace reviews, and detailed

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## New Review Paper Highlights **Gut-Brain Benefits** of **Novel Herbal Blend**, Digexin

**NXT USA (EDISON, NJ)** has announced the publication of a narrative review<sup>1</sup> that offers an in-depth analysis of the efficacy and safety of its Digexin ingredient, which is a novel blend of *Withania somnifera* root (Ashwagandha) and *Abelmoschus esculentus* (okra) extracts. The review highlights the relationship between gastrointestinal function and the brain, known as the gut-brain axis, and the utility of nutraceutical ingredients such as ashwagandha and okra individually and in combination as Digexin.

The findings demonstrate that the herbal blend impacts the gut-brain axis, supporting gastrointestinal function while also enhancing quality of life by reducing stress and enhancing sleep. For example, a recent randomized placebo-controlled study of 135 men and women found that participants taking either 300 mg or 500 mg of Digexin for 60 days experienced significant improvements in constipation symptoms, while also experiencing improvements in anxiety, depression, and sleep. Physiologically, these participants experience significant improvements in their levels of serotonin, gastrin, diamine oxidase (DAO), and anti-inflammatory cytokines as well as decreases in their levels of serum cortisol, zonulin, and pro-inflammatory IL-6.

"Improvements in serotonin and gastrin indicate enhanced secretion of gastric mucus and peristalsis," the researchers write. "Reductions in cortisol can lead to improved GI function. Lower cortisol levels are associated with decreased sympathetic activity and increased parasympathetic

activity. This shift increases blood flow to the GI tract, stimulates digestive enzyme secretion, and enhances GI motility. Serotonin is a neurotransmitter primarily known for its role in regulating mood and emotions in the brain. Serotonin transmits signals through the vagus nerve, which influences emotional and cognitive processes. Increases in serotonin improve mood, sleep, and anxiety."

"Until now, gut-health products really have only referred to the gut-brain axis in terms of modulating the gut for some downstream benefit for the mind or various other systems," said Erin Withee, director of ingredient innovation at Freeman Nutra, Digexin's manufacturer, in a press release. "Products that work through the mind to alleviate GI issues like constipation, indigestion, or reflux are effectively non-existent. Half of all GI disorders originate in the mind, and the mind arguably exerts the most influence over symptom presentation and intensity. Until Digexin, the number of brain-to-gut solutions had been zero."

"We believe Digexin will be a transformative addition to the market, offering manufacturers an innovative ingredient backed by robust research," added Eric Anderson, general manager of NXT USA, Digexin's distributor. "Our commitment to advancing natural health solutions is reflected in the rigorous research and development that went into Digexin."

“  
Half of all GI disorders originate in the mind, and the mind arguably exerts the most influence over symptom presentation and intensity.  
”

—Erin Withee, director,  
ingredient innovation,  
Freeman Nutra

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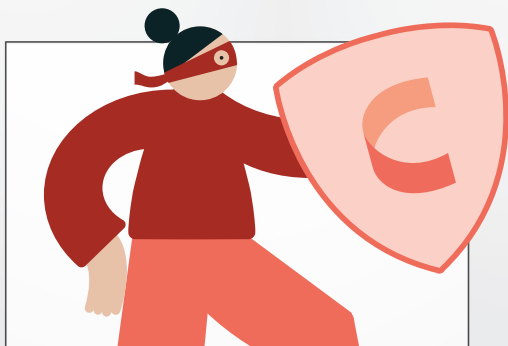
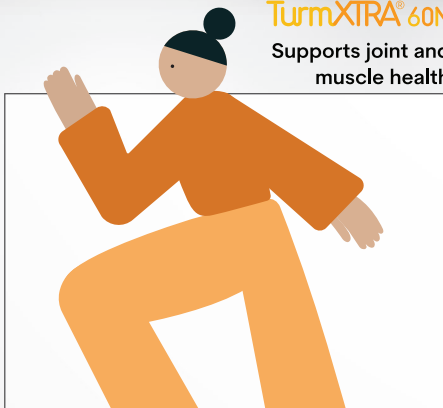
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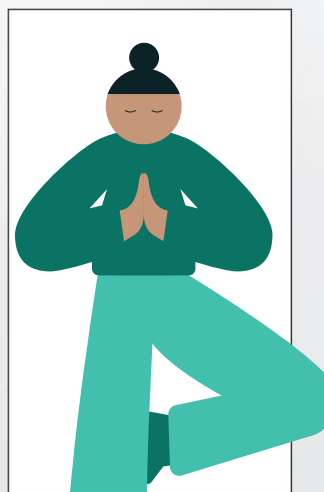
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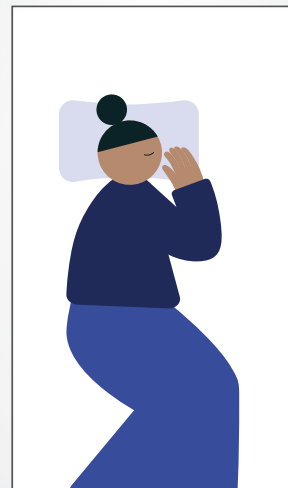
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# New Review from **BAPP** Estimates Adulteration of **Five Popular Botanicals**

**A RECENT REVIEW<sup>1</sup>** conducted by the nonprofit ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP) estimated the adulteration of popular herbs on the market, revealing the challenges of determining adulteration rates of other botanicals. The study focused on the adulteration of black cohosh rhizome, echinacea root or herb, elder berry, ginkgo leaf, and turmeric root/rhizome. The authors reviewed 78 publications with a total of 2995 samples. Of the 2995 samples, 818 were reported to be adulterated or mislabeled.

Ginkgo leaf had the highest level of adulteration with 56.7% of the 533 samples being adulterated, followed by black cohosh rhizome with 42.2% of its 322 samples being adulterated. Of the 200 echinacea samples, 695 elderberry samples, and 1247 turmeric root/rhizome samples, 28.5%, 17.1%, and 16.5% were adulterated, respectively. Licensed or registered herbal medicines had a lower risk of adulteration compared to products sold as dietary supplements, said the researchers.

One of the review's main takeaways is that the rate of adulteration substantially differs between ingredients. "Due to the significant limitations of the available data upon which the estimated extent of adulteration is based, and the rapidly changing botanical dietary supplement market, conclusions from the five herbs examined in this publication cannot be applied to other botanicals traded in the global

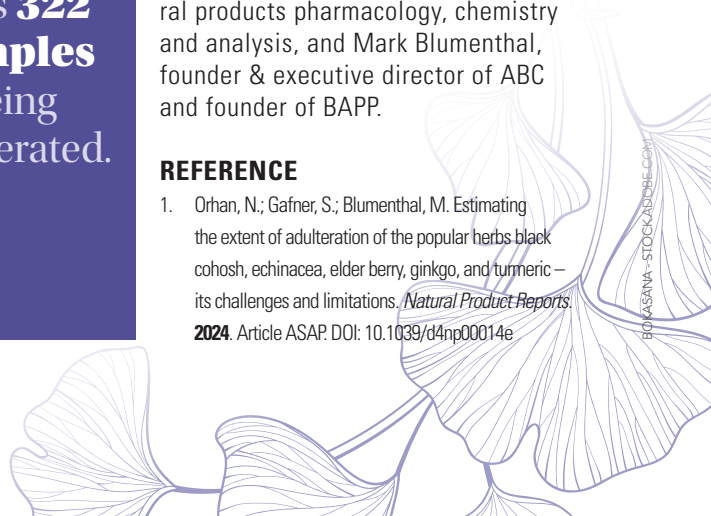
market," the authors write. "However, the data clearly show that a substantial portion of the botanical dietary supplements do not contain what is claimed on their labels."

According to BAPP, thirteen years of research and publications by the non-profit have found that almost 30 popular botanicals (so far) are subject to adulteration. Some adulteration is unintentional, but most is economically motivated. "The numbers obtained for the extent of adulteration of the five botanicals investigated for this systematic review may not be representative for the overall adulteration rate in the global herbal dietary and food supplement industry, but it is clear that adulteration of botanical ingredients is a problem and impacts a substantial portion of products sold as dietary or food supplement," said Stefan Gafner, PhD, in a press release. Gafner is one of the authors of the review, and the American Botanical Council's (ABC) chief science officer and BAPP director. The review was also authored by Nilüfer Orhan, PhD, an expert in natural products pharmacology, chemistry and analysis, and Mark Blumenthal, founder & executive director of ABC and founder of BAPP.

**Ginkgo leaf** had the highest level of adulteration with **56.7%** of the **533 samples** being adulterated, followed by **black cohosh rhizome** with **42.2%** of its **322 samples** being adulterated.

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## Tocotrienol-Treated **Neuronal Cells Experience Enhanced Cell Proliferation and Neurogenesis** in Recent *In Vitro* Study

**A RECENT *IN VITRO* STUDY<sup>1</sup>** found that hippocampal neuronal cells treated with tocotrienol-rich fractions saw enhanced cell proliferation and neurogenesis. As explained in the study, neurogenesis and long-term potentiation of neurons in the hippocampus influence memory formation. Additionally, vitamin E has previously demonstrated antioxidant, anti-inflammatory, and neuro-protective effects.

Building off the results of a previous randomized, placebo-controlled study on memory and attention span after two weeks of tocotrienol supplements, researchers aimed to better understand the mechanism and signaling pathways of this effect on a cellular level. Using two cell models, they examined the protein expression and localization in hippocampal HT22 neuronal cells using cells treated with tocotrienol-rich fractions from Davos Life Science.

Results showed that the cells treated with tocotrienol-rich fractions saw increases in cell proliferation through the activation of brain-derived neurotrophic factor/tropomyosin receptor kinase B pathway as well as elevated levels of key proteins, namely cyclin D and E, indicating an increase in cell cycle progression and proliferation. The increased phosphorylation of proteins like Ca<sup>2+</sup>/calmodulin-dependent protein kinase II and glutamate receptor 1 was observed could also lead to stronger synapses, essential for learning and memory, to improve reaction times and neural efficiency.

Davos Life Science is a subsidiary of Kuala Lumpur Kepong Berhad (KLK), a producer of phytonutrients. DavosLife E3 Tocotrienols contain the full spectrum of Tocotrienols and  $\alpha$ -Tocopherol, which have also been studied for their effects on heart health. The DavosLive tocotrienols are sourced from non-GMO palm fruits. KLK Oleo and Davos Life Science funded the research study.

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# Botanical Blend Supports **Skin and Scalp Health** in People Exposed to **Environmental Stressors**

**A RECENT STUDY<sup>1</sup>** found that a blend of standardized botanical extracts, called Zeropollution, may support scalp health under environmental stress. The blend, manufactured by Monteloeder, S.L. (Madrid, Spain), is made up of extracts of *Rosmarinus officinalis*, *Lippia citriodora*, *Olea europaea* leaf, and *Sophora japonica*. Previous research has shown that the blend may reduce oxidative stress-induced skin damage caused by air pollution, and enhance skin's resilience to environmental stressors.

In this most recent study, 66 women working outdoors in urban areas with high particulate matter levels were given either 250 mg of the botanical blend or placebo daily for 12 weeks. Researchers evaluated skin antioxidant status (FRAP), skin and scalp moisturization (corneometer), transepidermal water loss (teuameter), oiliness (sebumeter), skin radiance and color (spectrophotometer), elasticity and firmness (cutometer), wrinkle depth (image analysis), and scalp clinical evaluation. At the end of the study, women taking the botanical blend experienced a 21% increase in skin antioxidant status, a 9.5% increase in skin moisturization, a 24.9% increase in skin radiance, a 16.5% reduction in wrinkle depth, a 25.2% reduction in dark skin pigmentation, and a 19.3% reduction in skin oiliness. When it came to their scalps, women taking the botanical blend experienced a 14.1% increase in moisturization, a 13.8% decrease in transepidermal water loss, and a 16.2% reduction in sebum content. Researchers also observed that 71% of women with sensitive scalps experienced reduced redness.



"Zeropollution is a polyphenol-rich blend of natural botanicals with dual-action benefits," explained Nuria Caturla, PhD, Monteloeder's chief R&D officer, in a press release. "It nourishes and rejuvenates both your skin and scalp, helping to protect against environmental stressors while enhancing overall skin and scalp health. The result is a refreshed and revitalized appearance. This beauty-from-within formula also emerges as a highly relevant solution to the current trend of skinification."

Skinification, the press release explains is the concept of treating the scalp the same as facial skin. "Consumers are becoming increasingly aware of the link between hair quality and scalp health," said Marcos López,

U.S. sales director for Monteloeder, in a press release. "Today's informed consumers seek products that naturally soothe, hydrate, and enhance the scalp to alleviate common issues such as dandruff, itchiness, oiliness, and dryness, as well as to enhance hair vibrancy. This study confirms that the Zeropollution nutricosmetic goes beyond bare skin health to address scalp concerns as well."

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# Krill Oil Supports **Skin Barrier Function** According to Recently Published Studies

**TWO STUDIES RECENTLY** published together have found that krill oil supplementation may support skin barrier function. The two randomized, placebo-controlled, pilot studies investigated whether 1 g or 2 g of krill oil (Superba Boost from Aker BioMarine) impacted transepidermal water loss (TEWL) in healthy adults, with skin hydration, elasticity, and omega-3 index acting as secondary outcomes. Results showed that both doses of krill oil significantly reduced TEWL, and increased hydration as well as elasticity compared to placebo. Additionally, there was a significant linear relationship between these improvements and changes in participants' omega-3 index.

The researchers explain that good TEWL and hydration are indicative of a robust barrier function, which helps to safeguard against external irritants and supports processes such as cell turnover and repair. They cite animal studies that showed how krill oil suppressed the formation of wrinkles caused by UVB radiation but increasing skin collagen and hyaluronic acid content, as well as increase skin mRNA expression of hyaluronic acid and collagen-related genes. This points to a potential mechanism of action for krill oil. The researchers explain that collagen helps reduce TEWL by providing structural support to the skin, offering a more intact barrier that maintains firmness and elasticity while hyaluronic acid is a powerful humectant that attracts and holds water.

"For years we have looked at how krill oil, with its phospholipids and long-chain omega-3 fatty acids, can positively impact skin health," said Katina Handeland, PhD, director R&D, human nutrition for Aker BioMarine. "The skin is the body's largest organ, and its health and hydration rely on lipid and ceramide levels, which

are influenced by nutrition. Omega-3 EPA and DHA modulate the lipid composition of skin cell membranes and their associated lipid mediators, thereby supporting skin barrier function. Phospholipids have a unique molecular function enabling them to both attract and repel water, which enables them to retain water within the skin. Additionally, both dietary essential fatty acids and phospholipids have shown to give a positive impact on skin ceramide levels, which are known to decline with age. The positive results in these two trials help validate evidence from previous research by showing the positive impact krill oil has in improving skin barrier function and moisture retention."

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— Katina  
Handeland, PhD,  
director R&D, human  
nutrition, Aker  
BioMarine.

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# N-Acetylcysteine May Play a Role in Prevention of **Neuropsychiatric Risks** from **Adolescent Cannabis Exposure**

**A RECENTLY PUBLISHED STUDY<sup>1</sup>** found that the antioxidant, N-Acetylcysteine (NAC), could protect adolescent brains from developing anxiety and depressive behaviors caused by sustained exposure to tetrahydrocannabinol (THC). NAC, available as a dietary supplement, has been generally proposed as a treatment for neuropsychiatric conditions due to its ability to regulate neurotransmitter balance, regulate oxidative stress, and more.

As explained in the study, sustained exposure to THC in early adolescence can lead to “neuropsychiatric vulnerability, including mood and anxiety-related symptoms” later in life. In particular, nucleus accumbens (Acb), a common link for signaling pathways related to affective disorders and addiction, is susceptible to alteration by THC. Additionally, developing brains are sensitive to oxidative stress, which cannabis increases. Mood and anxiety disorders are associated with compromised antioxidant responses.

Using rodent models, the researchers tested the effect of THC on adolescent rats and the effects of NAC as an intervention. “We report that adolescent THC induces long-lasting anxiety and depressive-like phenotypes, concomitant with dissociable molecular and neuronal activity alterations in AcbSh vs. AcbC,” the researchers stated. “Remarkably, NAC administration normalized these THC-induced phenotypes while preventing dysregulations in metabolomic biomarkers associated with mood and anxiety-related pathophysiology.”

“Our study provides several novel discoveries linking the impacts of cannabinoid-induced striatal pathophysiology on markers for affective dysregulation which is a concerning risk factor for chronic adolescent cannabis use,” the researchers concluded. “Importantly, the present findings suggest that antioxidant interventions may serve as a potential pharmacotherapeutic approach to the prevention of neurodevelopmental disorders induced by cannabis exposure.”

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1. Publication Title: NUTRITIONAL OUTLOOK
2. Publication Number: 17607
3. Filing Date: 9-20-24
4. Issue of Frequency: Monthly except Jan/Feb & July/Aug combined
5. Number of Issues Published Annually: 10
6. Annual Subscription Price: \$228.00
7. Complete Mailing Address of Known Office of Publication (Not Printer): MULTIMEDIA HEALTHCARE LLC, 2 Commerce Drive, Cranbury, NJ 08512
8. Complete Mailing Address of Headquarters or General Business Office of Publisher (Not Printer): MULTIMEDIA HEALTHCARE LLC, 2 Commerce Drive, Cranbury, NJ 08512
9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor - Publisher: Stephanie Shaffer, MULTIMEDIA HEALTHCARE LLC, 485F ROUTE 1 S STE 210, ISELIN NJ 08830-3072; Editor: Sebastian Krawiec, MULTIMEDIA HEALTHCARE LLC, 485F ROUTE 1 S STE 210, ISELIN NJ 08830-3072; Managing Editor: Madeline Colli and Erin Mcevoy, MULTIMEDIA HEALTHCARE LLC, 485F ROUTE 1 S STE 210, ISELIN NJ 08830-3072
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11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages or Other Securities: None
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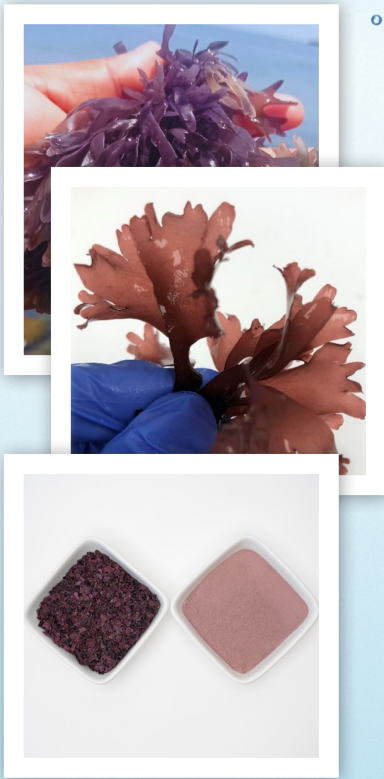




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**B**rands have been chasing perfection in the snack bar category for as long as it has existed. As with any product, there's always something to improve, and on top of it all, trends change over time, demanding progress. *Nutritional Outlook* recently interviewed Peter Rahal, founder of the protein snacks brand RXBAR, about his latest venture, David, a brand of protein bars that is designed to help build muscle while also helping with weight management. It was a valuable opportunity to understand how the bar category has changed and grown from one of the category's key innovators.

So, why did Rahal embark on developing another protein bar in an already saturated market? Well, according to Rahal, while the protein bar space is saturated, he does not find the category all that competitive. "That's because I don't think many great products are out there. That leaves room for a new product like David, which is very differentiated from a macronutrient perspective," explains Rahal. "With expert input from chief science officer Dr. Peter Attia, David delivers the highest protein per calorie of any bar on the market—approximately 50% more than our nearest competitor—without sugar or artificial sweeteners. This innovation sets David apart in a market that has largely been stagnant."

David bars are made up of a blend of proteins that include milk protein isolate,



## Perfecting the Bar

*Nutritional Outlook* interviewed the founder of RXBARs about his new brand, David.

by **SEBASTIAN KRAWIEC**, Managing Editor

collagen, whey protein concentrate, and egg white, each of which contribute something to the product. For example, the milk protein isolate and egg whites provide a complete amino acid profile, while also supporting muscle growth and recovery (David bars have a Protein Digestibility-Corrected Amino Acid Score of

1.0). The collagen assists in the bar's texture while supporting hair, skin, nail and joint health. The whey protein concentrate provides a fast-digesting protein that help with post-workout recovery. All this is quite the departure from RXBAR which obtains its protein content from egg whites and nuts. According to Rahal,

the market is moving in a different direction.

"RXBAR aligned with a nutrition trend of the time – paleo and a focus on natural ingredients," he explains. "Over time, I realized that 'natural' actually didn't mean 'healthy,' and I think the market did too, which is why paleo is not nearly as popular as it used to be. That's why I'm excited about David. The product philosophy is rooted in the truths of nutrition. High protein with low calories is not a trend; it's a proven way to increase muscle and decrease fat."

The goal of building muscle and decreasing fat not only taps into what consumers want, but also leverages an unsung benefit of protein, says Rahal. "Many don't realize that protein is also a massive lever for fat loss. It promotes satiety, making people feel fuller for longer. This leads to eating fewer calories and losing fat, all while maintaining muscle better than in a low-protein diet," he explains. "Additionally, protein is crucial for beauty-related bodily functions like forming healthy skin, hair, and nail cells. By offering a high protein content without excess calories, consumers can best meet their nutritional and aesthetic goals, all while enjoying a food they actually want to eat."

At the end of the day, says Rahal, success in the bar category "depends on offering high nutritional value and excellent taste/texture." **N**





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