

2019

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Recommended Citation

Glover, M. M. (2020). The Marketing of Self-Care and Alternative Therapies in the U.S. in 2019: How Industry Stakeholders Appeal to Consumers' Perceptions of Novel Food Products and Additives. *Journal of Food Law & Policy*, 15(2). Retrieved from <https://scholarworks.uark.edu/jflp/vol15/iss2/7>

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—Journal of—
FOOD & LAW
—POLICY—

Volume Fifteen

Number Two

Fall 2019

THE MARKETING OF SELF-CARE AND ALTERNATIVE
THERAPIES IN THE U.S. IN 2019: HOW INDUSTRY
STAKEHOLDERS APPEAL TO CONSUMERS' PERCEPTIONS
OF NOVEL FOOD PRODUCTS AND ADDITIVES

Melanie Marie Glover

The Marketing of Self-Care and Alternative Therapies in the U.S. in 2019: How Industry Stakeholders Appeal to Consumers' Perceptions of Novel Food Products and Additives

Melanie Marie Glover*

Abstract

This article examines the current marketing techniques of food products and additives in the growing self-care industry in print and digital formats. It assesses how well consumers understand such advertising tactics, and what the industry and federal government agencies are doing (or not doing) to help consumers be mindful and savvy about their purchase choices. The discussion further showcases hot-topic food products and additives including CBD, Kratom, and plant-based meat as examples of both regulatory risk and opportunity. Lastly, the article advocates a collaborative effort among federal government agencies (FDA, FTC, USDA, etc.), industry stakeholders, and the public to help accurately define not only the risks of food products and additives in the self-care space, but also the necessary regulations to keep consumers informed and empowered both in stores and online.

I. Introduction

How consumers understand the messaging around a consumer good is not a novel issue.¹ For decades, not only the United States (U.S.) federal and state governments, but also private industry stakeholders have toiled to protect the consumer from misleading product messaging.² However, given the rise in certain “natural,” self-care products containing food and other ingestible

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¹ See, e.g., *Kordel v. United States*, 335 U.S. 345, 349 (1948) (deciding issues surrounding advertising and labeling of consumer goods). See generally Ivan L. Preston, *Reasonable Consumer or Ignorant Consumer? How the FTC Decides*, 8 J. CONSUMER AFF. 131 (1974) (discussing various consumer protection standards).

² See, e.g., *Kordel*, 335 U.S. 345 (consumer protection case); see also Jonathan Stempel, *Five More U.S. States sue OxyContin Maker Purdue Pharma Over Opioid Epidemic*, REUTERS (May 16, 2019), <https://www.reuters.com> (search article title and select first result); see also Lenny Bernstein, *Five More States Take Legal Action Against Purdue Pharma for Opioid Crisis*, WASH. POST, (May 16, 2019), <https://www.washingtonpost.com> (search article title and select first result).

ingredients, that messaging is growing more complex, less understood, and more easily misconstrued.

Advertising and marketing strategies have hinged for years on the emotional and social value of food and food-related products, and their tactics have worked. Devour Tours, a Spanish start-up company, promotes itself with its values of connecting people to local culture (Spain, France, Portugal, and Italy) through the experiences of seeing, tasting, smelling, touching, and devouring foods and beverages.³ The *Culinaria* book series and *The Food Lover's Handbook* are other modern examples of food sold through authentic cultural lessons and culinary experiences.⁴ Even Starbucks' business model rests on connecting the consumer to his or her cup of joe along with comforting encounters with plush sofas and chairs.⁵ Similarly, by helping the consumer understand the emotional connection between a product and a desirable experience, marketers of self-care products are testing the waters by adapting their strategies to remain relevant and competitive,⁶ and they are just getting warmed up.

II. What is the "Self-Care" Industry, and Why is it Exploding?

The self-care industry is booming.⁷ In a time of ever-increasing healthcare costs,⁸ consumers prefer more options and

³ Devour Tours, *The Story Behind Devour Tours*, YOUTUBE (Mar. 1, 2017), <https://www.youtube.com/watch?v=ycoy68dwYIs>.

⁴ See generally MARION TRUTTER, *CULINARIA SPAIN: A CELEBRATION OF FOOD AND TRADITION* (2015) (a unique cookbook that offers cultural lessons with glimpses into various Spanish cooks' recipes and meal preparations through their personal and family stories in Spain); JODI ETTEBERG, *THE FOOD TRAVELER'S HANDBOOK* (Full Flight Press, 2012) (a former lawyer and current food guru's journey into Asian cuisine through travel, tourism, and curiosity).

⁵ Mitch Free, *Apple, Starbucks Sell Experiences, Not Products*, THE STREET (May 20, 2010), <https://www.thestreet.com/story/12806098/1/apple-starbucks-sell-experiences-not-products.html>.

⁶ IRI, *Taking Charge: Consumers Grabbing Hold of their Health and Wellness Drives \$450-Billion Opportunity*, 9 (Nov. 2018), https://www.iriworldwide.com/IRI/Media/Library/Publications/IRI_Self_Care_POV.pdf; Michele Parmelee, *Deloitte's Global Millennial Survey: Exploring a "Generation Disrupted."* FORBES (May 20, 2019), <https://www.forbes.com/sites/deloitte/2019/05/20/deloitte-globals-millennial-survey-is-full-of-surprises-not-necessarily-the-good-kind/#64d15874bc6a>.

⁷ See e.g., IRI, *supra* note 6, at 9; Erik Sherman, *U.S. Health Care Costs Skyrocketed to \$3.65 Trillion in 2018*, FORTUNE, (Feb. 21, 2019), <https://fortune.com/2019/02/21/us-health-care-costs-2/>; Neil Lister Interview: *Self Care Champion*, PAGB (June 17, 2019), <https://www.pagb.co.uk/about-pagb/self-care-champion-p3-lister/>.

⁸ Christopher Cheney, *Analysis: Doctor's Prescriptions for America's Broken Healthcare System*, HEALTHLEADERS, (July 18, 2019), <https://www.healthleadersm>

alternatives to manage their own health.⁹ “Self-care” means those “decisions people make or activities they participate in to ensure health and wellness for themselves and their families.”¹⁰ Self-care refers to the accumulated habits, benefits, and solutions that consumers implement themselves over time; in this way, self-care is preventive medicine, and it can cost less than prescription drugs for treatment.¹¹ Over-the-counter remedies are chief examples of such self-care products that consumers can control for themselves. “Alternative therapy,” the use of homeopathic products and other at-home remedies that tout themselves as being gentler for the human body, is another such example.¹²

Consumers nowadays also have access to more information than ever, and they are using it to explore self-care and alternative therapies to better control their well-being. Examples of trendy self-care consumer goods include: products marketed as “natural,” “chemical free,” lifestyle products, probiotics, vaping technologies, cannabidiol (“CBD”), food additives, dietary supplements, vitamins, nasal sprays, personal hygiene products, sleep remedies, body scrubs, skin care and other topical remedies, suntan products, oral care products, etc.¹³ The plethora of self-care, over-the-counter

edia.com/clinical-care/doctors-prescriptions-americas-broken-healthcare-system; see also Steven Porter, *Analysis: Azar and Verma: Competition, Value-Based Models Needed to Fix Our Cost Problem*, HEALTHLEADERS, (July 23, 2019), <https://www.healthleadersmedia.com/strategy/azar-and-verma-competition-value-based-models-needed-fix-our-cost-problem>.

⁹ IRi, *supra* note 6, at 2.

¹⁰ *Id.* at 1.

¹¹ *Id.* at 3.

¹² *Id.* at 2.

¹³ See IRi, *supra* note 6, at 6–7. A few examples of self-care consumer goods marketed in these ways include products found at the following websites: FOREST CENTER HERBS, <https://forestcenterherbs.com> (last visited Nov. 8, 2019); THRIVE MARKET, <https://www.thrivemarket.com> (last visited Nov. 8, 2019); SWANSON VITAMINS, <https://www.swansonvitamins.com> (last visited Nov. 8, 2019). Other “natural” self-care product examples include Land O’Lakes All-Natural Eggs, JIF Natural Creamy Peanut Butter, Seventh Generation Natural Laundry Detergent, Frito Lay Natural Cheetos White Cheddar Cheese Puffs, Neutrogena Naturals skincare products, Aveeno Active Naturals skincare products, Orville Redenbacher’s Naturals—Simply Salted Popcorn, and Hillshire Farm Naturals No Antibiotics Ever Slow Roasted Turkey Breast. See LAND O’LAKES, <https://www.landolakes.com/products/eggs/> (last visited Nov. 10, 2019); THE J.M. SMUCKER COMPANY, <https://www.jif.com/products/peanut-butter/natural-creamy-peanut-butter> (last visited Nov. 10, 2019); SEVENTH GENERATION, <https://www.seventhgeneration.com/laundry-detergent-free-clear> (last visited Nov. 10, 2019); FRITO LAY, <https://www.fritolay.com/products/simply-cheetos-puffs-white-cheddar-cheese-flavored-snacks> (last visited Nov. 10, 2019); NEUTROGENA, <https://www.neutrogena.com/naturals.html> (last visited Nov. 10, 2019); AVEENO, <https://www.aveeno.com> (last visited Nov. 10, 2019); ORVILLE REDENBACHER, <https://www.orville.com/naturals-simply-salted> (last visited Nov. 10, 2019);

options available is giving consumers a lot of reasons *not* to visit the doctor for a prescription.¹⁴

Digital health resources, online medical advice and e-visits, and personalized electronic marketing strategies are also emerging offerings in the self-care space due to consumer demand for convenience and the rise in online retailers marketing specialty, “more natural” consumables that are easily accessible for consumers.¹⁵ Burt’s Bees, the Honest Company, and other wellness companies are convincing consumers that their more “natural” products will help consumers feel better in their daily lives.¹⁶ The social media marketing of food and food-related products is also a hot topic among lawyers and legal professionals attempting to understand the current advertising landscape for such products.¹⁷ The rising self-care industry has developed slogans such as “Gen Well,”¹⁸ “better for me” products and therapies,¹⁹ and “free from [insert a chemical or ingredient].” Self-care and alternative therapies are available anytime to consumers digitally or over-the-counter in retail stores. Moving forward, the industry may develop even further

HILLSHIRE FARM, <https://www.hillshirefarm.com/products/deli-meat/naturals-slow-roasted-turkey-breast> (last visited Nov. 10, 2019).

¹⁴ IRI, *supra* note 6, at 1 (stating that 47% of millennials and 41% of Gen Xers avoid visiting the doctor).

¹⁵ See, e.g., *Digital Health Research Resources*, UNIV. OF CAL. SAN FRANCISCO RES. CONSULTATION, CLINICAL & TRANSITIONAL SCIENCE INSTITUTE, <https://consult.ucsf.edu/guidance/digital-health> (last visited Nov. 3, 2019); IRI, *supra* note 6, at 1; see also Serra J. Schlanger & Rachael E. Hunt, *Telemedicine, Understanding the FDA’s Role in Recent Regulatory and Enforcement Actions*, COMPLIANCE TODAY (July 2019), <https://compliancecosmos.org/telemedicine-understanding-fdas-role-recent-regulatory-and-enforcement-actions?authkey=410f81ecc4545f0d3d381cf44ac4529e69301e2ed123864ba2e129e2c38feec>.

¹⁶ See BURT’S BEES, <https://www.burtsbees.com/content/ingredients-1/> (last visited Nov. 5, 2019) (stating on each individual ingredient page that the ingredient is “[g]ood for you, naturally”); Ahiza Garcia, *The Skincare Industry Is Booming, Fueled by Informed Consumers and Social Media*, CNN (May 10, 2019, 11:30 AM), <https://www.cnn.com/2019/05/10/business/skincare-industry-trends-beauty-social-media/index.html>; see also *A ‘Natural’ Rise in Sustainability Around the World*, NIELSEN (Jan. 10, 2019), <https://www.nielsen.com/us/en/insights/article/2019/a-natural-rise-in-sustainability-around-the-world/>.

¹⁷ For example, the Food and Drug Law Institute hosted a conference in September, 2019 about label claims and substantiation, plant-based food products, and social media marketing. FOOD AND DRUG LAW INST., <https://www.fdi.org/2019/09/food-advertising-labeling-and-litigation-conference/> (last visited Nov. 10, 2019).

¹⁸ See Katie Nermoe, *Millenials: The ‘Wellness Generation’* (Sept. 12, 2018), <https://news.sanfordhealth.org> (when you access the site, search “Wellness Generation” in the search bar at the top right where it says, “What can we help you find?”; the first option will be the article by Katie Nermoe); GENWELL PROJECT, <https://genwellproject.org/> (last visited Nov. 7, 2019).

¹⁹ IRI, *supra* note 6, at 2.

ways to access these products. Still further, there has been an increase in recent years in the use of smart phone applications and personal counting devices, which range from watches to fitness bracelets, constantly measuring and storing data about an individual's state of health.²⁰

Despite the interrelated yet competing interests and novelty of this social, business, and medical phenomenon, self-care and alternative therapies may genuinely help provide wellness solutions for consumers' health issues.²¹ Consumers are seriously interested in greater self-management of their health conditions using products that empower them to proactively prevent or help treat health conditions.²²

Even given their growing enthusiasm for the self-care industry, however, consumers should be skeptical because many questions remain unanswered. These questions include but are not limited to: what does the product regulatory/consumer goods industry understand to be a "self-care" remedy or product; what is the "reasonable consumer" standard for understanding the marketing around a product;²³ are food products, dietary supplements, and other alternative therapies marketed differently nowadays than their counterparts were a decade or more ago; and what impact does this have on consumers' purchases? Additional industry-specific questions include: do industry stakeholders/food producers/dietary supplement manufacturers need to market differently new food, food additives, dietary supplements, and alternative therapies consumed

²⁰ *Id.*; Christopher Lane, *Digital Health and the Rise of Mental Health Apps*, PSYCHOLOGY TODAY (Aug. 11, 2018), <https://www.psychologytoday.com/us/blog/ide-effects/201808/digital-health-and-the-rise-mental-health-apps>.

²¹ See, e.g., Douglas Mann, et al., *Integrating Complementary & Alternative Therapies with Conventional Care*, in THE CONVERGENCE OF COMPLEMENTARY, ALTERNATIVE, & CONVENTIONAL HEALTH CARE: EDUCATIONAL RESOURCES FOR HEALTH PROFESSIONALS, 8–10 (Sheila N. Thomas ed., 2004), <https://www.med.unc.edu/phyrehab/pim/files/2018/03/Integrating.pdf>.

²² See, e.g., The Reis Group, *Survey Finds Patients Want More Guidance from Physicians on Self-Care*, EUREKALERT! (July 23, 2019), https://www.eurekaalert.org/pub_releases/2019-07/trg-sfp072219.php; GRAND VIEW RESEARCH, U.S. NATURAL PERSONAL CARE MARKET SIZE, SHARE & TRENDS ANALYSIS REPORT BY PRODUCT (SKIN CARE, HAIR CARE, ORAL CARE), BY DEMOGRAPHY (BABY, MIDDLE-AGED ADULTS, YOUNG ADULTS), AND SEGMENT FORECASTS, 2019-2025 (Feb. 2019), <https://www.grandviewresearch.com/industry-analysis/us-natural-personal-care-market>.

²³ FED. TRADE COMM'N, ADVERTISING FAQ'S: A GUIDE FOR SMALL BUSINESS, <https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business> (last visited Nov. 7, 2019) (stating that the "reasonable consumer" is the "typical person looking at the ad" and that the ad will be viewed "in context—words, phrases, and pictures—to determine what it conveys to consumers").

by humans (given the novel and nuanced nature of these products, the rising self-care and wellness industry, and the online selling of consumable food products and dietary supplements);²⁴ does online selling and consumers' increased access to food products, dietary supplements, and other alternative therapies present increased risks to consumers such that the marketing of these products needs to use more careful, precise, and transparent messaging and positioning; and do consumers understand the health risks and benefits of food products, food additives, dietary supplements, and alternative therapies sold online as well as they understand the same store-bought or traditional retailer-sold products?²⁵ Finally, what is the role of technology in relation to these self-care products (e.g. digital health, artificial intelligence, and online selling of self-care products) (e.g. public accessibility to food products and product descriptions and reviews as advertisements), and is the product for sale a food or a drug, and if both, how should it be regulated?²⁶ These questions

²⁴ See generally Vivekanand Sharma et al., *Identifying Complementary and Alternative Medicine Usage Information from Internet Resources: A Systematic Review*, 5 METHODS INF. MED. 322–332, (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4975632> (providing a broad overview of research relating to such concerns).

²⁵ See *Why Are Complementary and Alternative Therapies Harder to Evaluate? The Treatments Are Assumed to Be Safe*, AMERICAN CANCER SOCIETY, <https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/complementary-and-alternative-methods-and-cancer/why-ca-m-is-hard-to-evaluate.html> (last visited Nov. 7, 2019) (describing the problems that arise when alternative therapies such as herbal remedies advertise a product untruthfully, which poses the question of how companies offering legitimate alternative therapy options will verify and market their products to consumers); see also *Integrative Medicine: Find Out What Works*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/complementary-alternative-medicine/in-depth/alternative-medicine/art-20046087> (last visited Nov. 9, 2019) (giving guidance to consumers considering the use of alternative therapies and medicines and warning of potential pitfalls); NAT'L CTR. FOR COMPLEMENTARY AND INTEGRATIVE HEALTH, DEP'T OF HEALTH AND HUMAN SERVS., FINDING AND EVALUATING ONLINE RESOURCES, <https://nccih.nih.gov/health/webresources#hed2> (last visited Nov. 8, 2019) (addressing the concern that consumers searching for alternative therapies online may not be able to discern the good from the bad and offering particular advice for navigating the Internet for alternative therapies).

²⁶ Food and Drug Admin., *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments*, REGULATIONS.GOV (Apr. 3, 2019), <https://www.regulations.gov/document?D=FDA-2019-N-1482-0001> (explaining that where manufacturers have added CBD to food products, such products violate the FD&C Act because FDA has approved CBD as an active ingredient in a drug; this reality highlights the main FDA concern about how to regulate food products that contain active ingredients in approved drugs); *FDA Warns Company Marketing Unapproved Cannabidiol Products with Unsubstantiated Claims to Treat Cancer, Alzheimer's Disease, Opioid Withdrawal, Pain and Pet Anxiety*, FOOD AND DRUG ADMIN. (July 23, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-company-mark>

help shape the scope of the trending and lingering debate about government regulation over certain food-drug hybrid products, and the evaluation is just beginning.

III. Is There a Standard Level of Understanding that May Apply to All Consumers?

The Federal Trade Commission (“FTC”) is the leading authority on the reasonable consumer standard.²⁷ According to the FTC, a reasonable consumer is a typical one.²⁸ In cases of advertising uncertainty, the FTC focuses its analysis on whether the advertisement would have misled or deceived a reasonable, unsophisticated consumer.²⁹ For example, in the context of the FTC’s recent enforcement action against Amazon for misleading in-app purchases directed at children, the FTC reminded advertisers that “under the FTC Act, it’s wise to view your transactions from the perspective of a reasonable consumer, not a customer already familiar with your products and billing practices.”³⁰

One consumer-friendly marketing technique that self-care companies are using involves creating product packaging that resembles a food or beverage product to demonstrate more natural, less-processed benefits to human health.³¹ A second marketing technique is personalization and customization to comply with consumers’ preferences by using consumer insights research.³² Still another technique “embrace[s] wellness-focused lifestyles” or experiences (e.g. rock-climbing and dancing, eating whole foods, etc.).³³ Finally, there is the convenience and efficiency of online nutritional counseling and medical and health-related advice.³⁴ These

eting-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer; *FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns*, FOOD AND DRUG ADMIN. (Nov. 25, 2019), <https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details> (announcing that FDA sent warning letters to 15 companies challenging their sales of CBD-infused dietary supplements and human and animal foods).

²⁷ Preston, *supra* note 1.

²⁸ *Down...But Not Out: Advert. and Labeling of Feather Down*, FED. TRADE COMM’N (Mar. 2019), <https://www.ftc.gov/tips-advice/business-center/guidance/do-wnbut-not-out-advertising-labeling-feather-down-0>.

²⁹ *Id.*

³⁰ Lesley Fair, *7 Quotes of Note from the Amazon Decision*, FED. TRADE COMM’N (May 3, 2016, 12:23 PM), <https://www.ftc.gov/news-events/blogs/business-blog/2016/05/7-quotes-note-amazon-decision>.

³¹ IRI, *supra* note 6, at 8–9.

³² *Id.* at 10–11.

³³ *Id.* at 5, 7.

³⁴ *Id.* at 11.

techniques are among the more positive, less misleading ones. The deception, however, lies in the claims—both explicit and implicit—of health-related consumer goods products.

IV. What is the Regulatory Framework for Food-Related Health Claims?

The Food and Drug Administration (“FDA”) regulates three types of health claims.³⁵ The first is nutrient content claims, which characterize the level of nutrients in a food (e.g. “high,” “low,” or “free of” fats, sodium, and other nutrients).³⁶ The second type of claims the FDA regulates are “structure-function” claims, which tell a consumer how beneficial a product could be for their health (e.g. “calcium builds strong bones”).³⁷ The third type of claims are qualified health claims.³⁸ Qualified health claims include statements about how certain food products may reduce the risk of disease or other health-related conditions (e.g. products claiming they can lower the consumer’s chance of heart disease or cholesterol levels).³⁹ The issue with food products and additives today is that their accompanying claims may fall into two or more of these areas. This reality challenges the FDA’s current framework of regulating drug messaging or drugs positioned as foods because: what if the product is or could be both?

V. What are Today’s Popular Food Products and Additives, and How are they Advertised?

The current commercial landscape for food-related products includes novel products such as plant-based food and food additives (e.g. meat, milk, mayonnaise, CBD, and other plant-infused products) that appeal to environment and human health-conscious consumers whose interests include weight and pain reduction and management.⁴⁰ Marketers for food manufacturers are selling these products as a healthy, self-care, or euphoric experience by creating a

³⁵ *Label Claims for Conventional Foods and Dietary Supplements* FOOD AND DRUG ADMIN. (June 19, 2018), <https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Heather Kelly, *Can the New Vegan Impossible Burger Fool Meat Lovers*, CNN BUS. (Jan. 8, 2019), <https://www.cnn.com/2019/01/08/tech/impossible-burger-new-recipe/index.html> (quoting David Lipman, Impossible Foods’ Chief Science Officer); Jordan Valinsky, *Tim Horton Will Start Selling Beyond Meat Sandwiches Across Canada*, CNN BUS. (June 12, 2019), <https://www.cnn.com/2019/06/12/business/beyond-meat-tim-hortons/index.html>.

message that encourages an emotional or social response from using or interacting with the product.⁴¹ There is also a market trend toward inserting plant-based food additives into food or dietary supplements and using them as an attractive, eye-catching ingredient in other consumable products.⁴² This discussion focuses on these product categories, but the marketplace is ripe with several other types of food products and dietary supplements with similar claims issues of which consumers should beware.

Plant-based products currently in the public and regulatory eye include CBD, Kratom, and plant-based meat.⁴³ This paper discusses how manufacturers and retailers market these plant-derived foods and food additives, how consumers understand such advertisements, and the potential health risks involved. This discussion ends with a glimpse into the regulatory framework (or lack thereof) for advertising these products. Finally, the paper sets forth potential solutions that industry stakeholders, the U.S. federal government, and consumers can advocate for and implement in the near future and in the long-term.

A. CBD

Regulatory concern is most prominent in the CBD arena because CBD is popping up everywhere.⁴⁴ Convenience stores, pharmacies, and even strip malls increasingly boast CBD

⁴¹ Sonia Thompson, *2 Lessons In Inclusive Marketing From KFC and Burger King's Popular Launches of Plant Based 'Meat'*, FORBES (Aug 31, 2019, 01:45 PM), <https://www.forbes.com/sites/soniathompson/2019/08/31/2-lessons-in-inclusive-marketing-from-kfc-and-burger-kings-popular-launches-of-plant-based-meat/#57755b152822>.

⁴² July through August 2019, a drive down Highway I-131 near the downtown Grand Rapids, Michigan area revealed a large display sponsored by Harvest Health Foods, a local grocery store chain, with "CBD" displayed in big, bold letters across the billboard, broadcasting the benefits of CBD. *CBD Oil*, HARVEST HEALTH FOODS, <https://harvesthealthfoods.com/tags/cbd-oil> (last visited Nov. 26, 2019).

⁴³ See U.S. FOOD & DRUG ADMIN., FDA REGULATION OF CANNABIS AND CANNABIS-DERIVED PRODUCTS, INCLUDING CANNABIDIOL (CBD) (Oct. 16, 2019), <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd> [hereinafter U.S. FOOD & DRUG ADMIN., FDA REGULATION OF CANNABIS]; see also U.S. FOOD & DRUG ADMIN., FDA AND KRATOM (Sept. 11, 2019), <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>; see also U.S. FOOD & DRUG ADMIN., STATEMENT OF POLICY – FOODS DERIVED FROM NEW PLANT VARIETIES (Apr. 29, 2019), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statement-policy-foods-derived-new-plant-varieties>.

⁴⁴ See Parija Kavilanz, *Suddenly CBD is Everywhere. Here's What's Next*, CNN BUS. (Mar. 26, 2019), <https://www.cnn.com/2019/03/26/success/cbd-entrepreneurs/index.html>.

inventory.⁴⁵ To start, the *Cannabis sativa* plant comes from the Cannabaceae plant family, and it contains active chemical compounds such as delta-9-tetrahydrocannabinol (“THC”) and CBD.⁴⁶ The Federal Controlled Substances Act (“CSA”) has controlled parts of the plant since 1970 under the drug class “Marihuana.”⁴⁷ “Marihuana” is listed in Schedule I of the CSA because of the psychoactive effects of THC, and the federal definition of “Marihuana” is “all parts of the plant *Cannabis sativa* L.”⁴⁸ The Farm Bill of 2018 legalized the sale of hemp-derived products while directing the U.S. Department of Agriculture (“USDA”) to develop regulations clarifying hemp use on a federal level.⁴⁹ The gap, however, arose when Congress stayed silent on the FDA’s role in regulating products derived from cannabis or hemp under the Food Drug and Cosmetics Act (“FD&C Act”). Some industry stakeholders have advocated for Congress to consider carving out an exception under the “Marihuana” definition to exclude cannabidiol from its definition like hemp.⁵⁰

The wide availability of CBD—evidenced by its various advertising forms—leads consumers to believe that it is lawful to purchase and consume. The following photos depict real-life advertisements of CBD for sale in the West Michigan area.

⁴⁵ See Sean Williams, *CBD: Coming to Chevron, Shell, ARCO, BP, Sunoco, or 76 Station Near You*, FOOL (June 14, 2019), <https://www.fool.com/investing/2019/06/14/cbd-coming-to-a-chevron-shell-arco-bp-sunoco-or-76.aspx>; see also Sean Williams, *This CBD Stock is Quietly Becoming a Retail Giant*, FOOL (July 13, 2019), <https://www.fool.com/investing/2019/07/13/this-cbd-stock-is-quietly-becoming-a-retail-giant.aspx>.

⁴⁶ See U.S. FOOD & DRUG ADMIN., FDA REGULATION OF CANNABIS, *supra* note 43.

⁴⁷ 21 U.S.C. § 802(16)(A) (2019).

⁴⁸ *Id.*

⁴⁹ 7 U.S.C. § 5940 (2019).

⁵⁰ 21 U.S.C. § 802(16)(B)(i) (2019); Sarah Sorscher, Deputy Dir. of Regulatory Affairs, Ctr. for Sci. in the Pub. Interest, Presentation at the FDLI Annual Conference: Marijuana, CBD, and Hemp: Understanding the Current Regulatory Landscape and How it Might Change (May 3, 2019).



Figure 1. CBD Advertisement in a Big Rapids, Michigan Strip Mall, June 30, 2019.⁵¹



Figure 2. CBD ReThink Display in Allegan, Michigan, Allegan Community Pharmacy, May 15, 2019.

⁵¹ The advertisement disappeared on Sunday, July 7, 2019. Similarly, an online retailer, Thrive Market, pulled CBD products in June 2019 after its merchant processor expressed concern over the products' legal status. In addition, Curaleaf Inc., a cannabis company, removed health claims about CBD products from its website after receiving a warning letter from the FDA in July 2019.

The FDA is focused on the cumulative exposure to CBD across a broad range of products. This is because edibles may have a longer delay in onset than inhaled products, difficult to control dosage, and higher risk of poisoning.⁵² The pricing, direct, and implied claims on a product may also cause confusion for a consumer.⁵³ For example, does putting a premium price on a CBD product suggest or imply a claim that it is valuable for some specific—albeit unspoken—purpose? What claims might a company be making by not saying anything?

The images below represent a fictional advertisement (although inspired by a real website and company)⁵⁴ of CBD claims to further illustrate regulatory concerns about its widespread sale. This exercise demonstrates the expansive range of legal issues related to explicit and implicit claims involved in the marketing of an emerging self-care health product like CBD-infused nasal spray.



Figure 3. Fictional CBD Product.

⁵² Daniel G. Barron et al., *Tasty THC: Promises and Challenges of Cannabis Edibles*, METHODS REPORT PRESS (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260817>.

⁵³ Riëtte van Laack, *FDA Encourages Food Industry to Use “Best if Used by” Date for Self-Stable Foods*, FDA LAW BLOG (June 4, 2019), <http://www.fdalawblog.net/> (search “FDA Encourages Food Industry”).

⁵⁴ The inspiration for the product can be found at the following website, however, all claims and copy on the images included in this research paper were created for educational and discussion purposes: <https://hhoutlet.com/products/hemp-cbd-nasal-spray-new>. Graphics by Theresa Fernández, <http://www.theresafernandez.com/>.



Figure 4. Advertisement of Fictional CBD Product.

The advertisement in Figure 4 showcases a multitude of the FDA’s concerns about the presence, labeling, and marketing of CBD as an ingredient in food products, dietary supplements, and cosmetics. The sale of these products over the Internet adds to the FDA’s concern for consumers who have little to no opportunity to interact with a knowledgeable salesperson or health professional; there is oftentimes no pharmacist available to answer questions digitally (yet). Unfortunately, the rise in digital health mixed with novel products means more room for misdiagnoses and human error in the mismanagement of treatments, prescriptions, and medicine consumption. The electronic marketing mediums also carry their own risks inherent to advertising products on the Internet or through applications;⁵⁵ the risk for misinterpretation and lack of information due to the speed at which consumers browse the Internet and scroll and click through their smart phones increase the likelihood of a misinformed or underinformed consumer.⁵⁶

This product demonstrates the numerous issues that the FDA and FTC can and should regulate. First, the claim, “Healthy Hemp-

⁵⁵ Miranda Brookins, *Disadvantages of Online Advertising Options*, CHRON (Feb. 5, 2019), <https://smallbusiness.chron.com/disadvantages-online-advertising-options-10212.html>.

⁵⁶ U.S. FOOD & DRUG ADMIN., VAPEJOOSE INC. WARNING LETTER, MARCS-CMS 585917 (June 18, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vapejoose-inc-585917-06182019> [hereinafter US. FOOD & DRUG ADMIN., VAPEJOOSE LETTER] (explaining that it is the responsibility of the manufacturer or distributor of the food, drug, or cosmetic “to ensure that [its] tobacco products and all related labeling and/or advertising on [its] website[s], on any other websites (including e-commerce, social networking, or search engine websites), in any other media in which [it] advertise[s], and in any retail establishments comply with each applicable provision of the FD&C Act and FDA’s implementing regulations”).

CBD Lavender-Scented Nasal Spray,” is misleading because hemp and CBD are now regulated differently after the passage of the Farm Bill of 2018.⁵⁷ Likewise, the meaning of “healthy” has not yet been (re)determined on a federal level despite receiving FDA enforcement attention;⁵⁸ therefore, there exists risk of consumer confusion in using this term. Second, the claims that the CBD can “manage pain, treat seizures, and prevent the early onset of dementia” are unapproved drug claims because they convey that the product’s intended use is to treat or prevent dementia and seizures and otherwise affect the structure and function of the human body, and therefore the sentence is misleading.⁵⁹ Third, the suggested dose

⁵⁷ Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments, 84 Fed. Reg. 12, 969 (Apr. 3, 2019) (to be codified at 21 CFR pt. 15) (explaining that the Farm Bill of 2018 removed hemp from the United States Controlled Substances Act, which means that cannabis plants and their derivatives with no more than 0.3 percent delta-9 tetrahydrocannabinol concentration (“THC”) are no longer controlled substances under United States Federal Law); U.S. FED. TRADE COMM’N, FTC POL’Y STATEMENT ON DECEPTION, (Oct. 14, 1983), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf; U.S. FOOD & DRUG ADMIN., USE OF THE TERM HEALTHY ON FOOD LABELING (Oct. 22, 2018), <https://www.fda.gov/food/food-labeling-nutrition/use-term-healthy-food-labeling>; U.S. FOOD & DRUG ADMIN., WARNING LETTER TO CURALEAF INC., MARCS-CMS 579289 (July 22, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/curaleaf-inc-579289-07222019> (explaining the FDA’s concerns that Curaleaf Inc.’s “CBD Lotion,” “CBD Pain-Relief Patch,” “CBD Tincture,” and “CBD Disposable Vape Pen” products are unapproved new drugs sold and misbranded in violation of the FD&C Act because the company included unapproved claims in the advertising related to these products on its website, and such claims were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body); Anna Edney & Craig Giammona, *FDA Targets U.S. Marijuana Leader in CBD Marketing Crackdown*, BLOOMBERG (July 23, 2019), <https://www.bloomberg.com/news/articles/2019-07-23/fda-targets-u-s-marijuana-leader-in-crackdown-on-cbd-marketing>.

⁵⁸ U.S. FOOD & DRUG ADMIN., WARNING LETTER TO KIND, LLC (Mar. 17, 2015), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kind-llc-03172015>; Angelica LaVito, *FDA to Consider What ‘Healthy’ Means and Other Claims Food Companies Can Make*, CNBC (Mar. 29, 2018), <https://www.cnbc.com/2018/03/29/fda-to-consider-updating-health-claims-food-manufacturers-can-make.html>; Deena Shanker & Anna Edney, *FDA to Update Its Definition of ‘Healthy’ This Summer*, BLOOMBERG (Mar. 29, 2019), <https://www.bloomberg.com/news/articles/2019-03-29/fda-will-give-definition-of-healthy-this-summer-gottlieb-says>.

⁵⁹ 21 § U.S.C. 321(g)(1) (2012) (stating the definition of “drugs” as intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body); *see also* Kordel, 335 U.S. 345 (discussing the scope of the Act’s “labeling” definition); *see also* U.S. FOOD & DRUG ADMIN., WARNING LETTER TO NUTRAPURE LLC (2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigati>

states “take as needed.” This statement raises the FDA’s well-known concern about the efficacy of CBD: how much spray is needed for the product to “work?”⁶⁰ Fourth, the optics of the marijuana leaves on the nasal spray bottle packaging with lavender accent colors may make implied claims; in other words, consumers may interpret these graphics to mean that the nasal spray product contains a pharmacologically active ingredient or THC, or that it produces some other psychotropic effect.⁶¹ Fifth, the claim that “nasal delivery means quick absorption; gummies and capsules can take up to an hour!” lacks supporting research as of the time of writing this paper. The FDA’s concerns are with dosage levels due to the various forms that CBD can be ingested. What if a person consumes both gummies and a nasal spray within a limited amount of time? How will the FDA regulate such dosages? Currently, there is no warning about the effect on the human body of taking CBD in multiple forms, and the FDA has invited industry stakeholders to conduct and share this research for increased understanding about CBD’s effects when combined in various ingestible products.⁶² Sixth, the language “read about our blog post on the therapeutic effects of Healthy Hemp-CBD Lavender-Scented Nasal Spray HERE” is problematic because the blog post may contain additional unapproved drug claims or other misleading language that encourage a consumer to purchase the CBD product. The question becomes whether the content on the blog contains additional advertising or labeling about the product due to the proximity of the link to the product (on the product packaging).⁶³

ons/warning-letters/nutra-pure-llc-567714-03282019 (demonstrating the FDA’s enforcement action against a dietary supplements company where the FDA criticized the company’s claims that CBD could help treat Alzheimer’s disease and anxiety-related disorders). As of the writing of this paper, FDA has only approved one cannabis-derived and three cannabis-related drug products. See U.S. FOOD & DRUG ADMIN., FDA REGULATION OF CANNABIS, *supra* note 43.

⁶⁰ Sorscher, *supra* note 50.

⁶¹ Leslie Lake, *New Research on CBD Highlights Immense Consumer Confusion and Erroneous Assumptions*, GROCERY MFRS. ASS’N (Oct. 28, 2019), <https://www.gmaonline.org/news-events/newsroom/new-research-on-cbd-highlights-immense-consumer-confusion-and-erroneous/> (Thirty-nine percent of Americans “incorrectly believe CBD is just another name for marijuana and more than half mistakenly think it can get you ‘high.’”).

⁶² The FDA established a docket for public comment for a notice published on April 3, 2019 to receive comments from industry stakeholders about CBD production, distribution, and sale. Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments, 84 Fed. Reg. 12, 969 (Apr. 3, 2019) (to be codified at 21 CFR pt. 15).

⁶³ The cases, *Kordel v. U.S.* and *U.S. v. 24 Bottles Sterling Vinegar & Honey*, demonstrate the distinction between when material is considered advertising (under FTC jurisdiction) and when material is considered a label or labelling (under FDA jurisdiction). *Kordel*, 335 U.S. at 347–51; *U.S. v. 24 Bottles Sterling Vinegar & Honey*, F.2d 157, 158–59 (1964).

Sellers of such products must be aware that related advertising material such as a blog post or an online article may be interpreted to be part of the product labeling and, therefore, subject to FDA regulations just like traditional product labels.⁶⁴ Finally, the “try other Healthy Hemp products” section featuring other CBD-infused products creates concerns that (1) these products may have unapproved drug claim issues, and that (2) the lack of warnings about the effects on the human body when taking two or more simultaneously may harm consumers. To address this, in the spring of 2019, the FDA invited industry stakeholders to submit their research findings on the effect of various CBD-infused products to help the FDA begin to understand how these CBD-infused products may affect humans if ingested together depending on the dosage.

The issue of food fraud, as it relates to the Cannabis plant and children, is also a risk to consumers that concerns the FDA.⁶⁵ A recent case involving THC-infused gummies (“Stoney Kids,” a candy in packaging eerily resembling that of the popular candy, “Sour Patch Kids”) reveals growing anxiety over the marketing of edibles to children by mimicking common snacks and candies.⁶⁶ Mondelez Canada has not only sued the manufacturer of the THC-infused gummies for trademark infringement and dilution; the Sour Patch Kids manufacturer also alleges that Stoney Kids violates California’s Medicinal and Adult-Use Cannabis Regulation and Safety Act because Stoney Kids directly targets children with its striking resemblance to Sour Patch Kids.⁶⁷ The timing of the Stoney Kids suit is particularly concerning considering the national and state-level debates occurring over CBD, THC, and related plant-derived food additives.

B. Kratom

Yet another ingestible self-care product is Kratom.⁶⁸ While not as much of a household name as CBD arguably is, Kratom is

⁶⁴ See *Kordel*, 335 U.S. at 351; *24 Bottles of Sterling Vinegar & Honey*, 338 F.2d at 159.

⁶⁵ Corinne Gretler, *Baby Food Has Too Much Sugar and Is Marketed Wrongly, WHO Says*, BLOOMBERG (July 15, 2019), <https://www.bloomberg.com/news/articles/2019-07-15/baby-food-has-too-much-sugar-and-is-marketed-wrongly-who-says>.

⁶⁶ Elaine Watson, *‘Virtual knockoff’: Mondelez Canada Warns of Growing Trend Towards Marketing Edibles by Ripping Off Popular Snacks and Candies*, FOOD NAVIGATOR USA (July 26, 2019), <https://www.foodnavigator-usa.com/Article/2019/07/26/Virtual-knockoff-Mondelez-warns-of-growing-trend-towards-marketing-edibles-by-ripping-off-popular-snacks-and-candies>.

⁶⁷ *Id.*

⁶⁸ Schedules of Controlled Substances: Temporary Placement of Mitragnine and 7-Hydroxmitragnine Into Schedule 1, 81 Fed. Reg. 59,929, 59,930 (proposed Aug. 31, 2016) (to be codified at 21 C.F.R. pt. 1308).

similar to CBD in that it is underregulated, is for sale online and over-the-counter,⁶⁹ has alleged psychotropic and therapeutic effects, comes from a plant, and can be added to food. Kratom's scientific name is *Mitragyna Speciosa*, derived from a tropical tree indigenous to Southeast Asia.⁷⁰ While Kratom and CBD have different regulatory histories (as of the writing of this paper, the U.S. Drug Enforcement Agency has announced its intent to schedule Kratom as a controlled substance),⁷¹ their similarities are significant. This means that market and consumer interest in Kratom are just as concerning as CBD for many of the same reasons. However, Kratom may deserve more immediate attention from regulators based on allegations that it can produce euphoric or psychotropic effects comparable to those that opioids produce in humans.⁷² While consumer-facing efficacy claims about Kratom range from mild to effective for managing pain, the regulatory dust is far from settling on Kratom. In an interview with Michigan Public Radio on July 17, 2019, University of Michigan Addiction Treatment Services psychiatrist, Edward Jouney, warned consumers to "scrutinize the source" from which Kratom is coming because "this is something that has the potential to be very powerful" for vulnerable populations who tend toward addictive behavior.⁷³ The FDA has also publicly denounced Kratom, warning consumers that its health impact is not yet well understood.⁷⁴ Like CBD, dosages for Kratom are not yet well-researched, leaving consumers precariously exposed to likely unjustified claims.

C. *Plant-Based Meat, Mayonnaise, and Milk*

CBD and Kratom are not the only products on the market that concern the FDA and FTC. Plant-based food options—and their advertising claims—are growing in popularity among health-conscious consumers who are interested in plant-based products due

⁶⁹ See, e.g., KRAKEN KRATOM, <https://krakenkratom.com/>.

⁷⁰ Schedules of Controlled Substances, 81 Fed. Reg. at 59,930.

⁷¹ *Id.*, at 59,933; DRUG ENF'T ADMIN., DEA Announces Intent to Schedule Kratom, Press Release (August 30, 2016).

⁷² See Jennifer Clopton, *Regulations Are on Hold as Kratom Debate Rages*, WEBMD (Feb. 11, 2019), <https://www.webmd.com/mental-health/addiction/news/20190211/regulations-are-on-hold-as-kratom-debate-rages>.

⁷³ You can buy it in gas stations, but experts warn that the drug Kratom is unregulated and under-researched. MICH. RADIO NPR (July 17, 2019), <https://michigan.drupal.publicbroadcasting.net/post/stateside-funding-roads-local-taxes-risks-kratom-mi-astronaut-apollo-11s-legacy>.

⁷⁴ Nick Wing, *Feds Prepare for a New War on Kratom, an Herbal Drug Many Swear By*, HUFFPOST (Nov. 14, 2017), https://www.huffpost.com/entry/fda-kratom-regulation_n_5a0b465be4b00a6eece4c9e0; FOOD AND DRUG ADMIN., Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom, Press Release (Nov. 14, 2017).

to their uneasiness with an overreliance on animal food products as a main source of protein. Consumers are also interested in more environmentally sustainable practices that use fewer resources, and plant-based product manufacturers proudly acknowledge this.⁷⁵ Impossible Foods, Inc. (“Impossible Foods”) is one example of a company focused on “eliminat[ing] the need for animals in the food system.”⁷⁶ To get there, the company has dedicated itself to “com[ing] up with a plant-based meat that people will actually choose.”⁷⁷

Food labels are also changing, and plant-based meat is a prime example of this.⁷⁸ Changing food labels speak to consumers’ changing attitudes toward food and its ingredients, which are consistent with their interests in the self-care industry. Consumers are choosier about their ingredients as they search for “dairy free,” “gluten free,” “egg free,” “cruelty free,” “fat free,” “hormone free,” and similar labels.⁷⁹ Consumers want to know what is and is not in their food, but not at the expense of quality and an authentic user experience. The growing number of “healthy” restaurant options and food brands demonstrate that consumers continue to care about what their food looks, smells, and tastes like.⁸⁰ Consumers do not want to

⁷⁵ *Impact Report 2019*, IMPOSSIBLE FOODS (2019), <https://impossiblefoods.com/mission/2019impact/>.

⁷⁶ Kelly, *supra* note 40 (quoting David Lipman, Impossible Foods’ Chief Science Officer).

⁷⁷ *Id.*

⁷⁸ See Julia Horowitz, *Meatless Farm Breaks into Booming US Market with Whole Foods Deal*, CNN BUS. (June 24, 2019), <https://edition.cnn.com/2019/06/24/business/meatless-farm-whole-foods/index.html> (explaining via a video, titled “Fake Meat is the Future. Here’s Why,” that the packaging for plant-based meat is more akin to that of their real meat counterparts than packaging geared toward vegan or vegetarian consumers, as well as some concerns around grocery store placement of plant-based meats); see also Jordan Valinsky & Danielle Wiener-Bronner, *America is Running Out of Impossible Burgers*, CNN BUS. (Apr. 30, 2019, 2:47 PM), <https://www.cnn.com/2019/04/30/business/impossible-meat-shortage/index.html>; see also Neil Vigdor, *Mission Impossible? Maker of Plant-Based Burger Struggles to Meet Chains’ Demand*, N. Y. TIMES (June 15, 2019), <https://www.nytimes.com/2019/06/15/business/impossible-foods-burger-demand.html>.

⁷⁹ See Brandon McFadden, *‘Gluten-Free Water’ Shows Absurdity of Trend in Labeling What’s Absent*, OBSERVER (Aug. 31, 2018, 11:29 AM), <https://observer.com/2017/08/gluten-free-water-shows-absurdity-of-trend-in-labeling-whats-absent-food-safety-regulations-consumers/>. A recent example is Palazzolo’s Artisan Dairy Slushie product, which bears a label containing the words, “No Fake Anything,” “No Trans Fat,” “No Gluten,” “No Added Hormones,” “No Corn Syrup,” and “No Dairy or Fake Flavorings.” See *Artisan Fruit Slushies*, PALAZZOLO’S ARTISAN DAIRY (2019), <https://www.palazzolosdairy.com/products/artisan-fruit-slushies/>.

⁸⁰ See Gary Stern, *CoreLife Eatery: A Vegetarian Restaurant Chain That Has Doubled Its Revenue in One Year*, FORBES (Mar. 25, 2019, 12:32 PM), <https://www.forbes.com/sites/garystern/2019/03/25/corelife-eatery-a-vegetarian-restaurant-chain-whose-revenue-doubled-in-one-year/#2acc04b07bbf>. CoreLife

ingest red meat, but they still want the experience of eating it. A recent example is the color additive petition that Impossible Foods filed and the FDA granted, allowing Impossible Foods to apply soy leghemoglobin—“plant blood”—to plant-based beef.⁸¹ Despite this, the FDA and the public are still very much concerned with the potential impact to human health that plant-based products may have.⁸²

Despite market interest, the FDA, USDA, and various food industry stakeholders have expressed their concerns regarding the marketing claims surrounding alternative protein food options.⁸³ The various parties’ interests have culminated in a complex and sensitive regulatory and commercial framework that supports cell-based meat production: the FDA regulates cell collection and growth

Eatery, Panera Bread, Qdoba, and other food chains are examples of restaurants advertising “healthier” and “cleaner” food options. See *100% of our food is 100% clean.*, PANERA BREAD (2019), <https://www.panerabread.com/en-us/articles/100-percent-of-our-food-is-100-percent-clean.html>; *Why Qdoba*, QDOBA MEXICAN EATS (2019), <https://www.qdobafranchise.com/why-qdoba>. See generally Leanna Garfield, *10 Up-and-Coming Healthy Fast Food Chains that Should Scare McDonald’s*, BUS. INSIDER (Feb. 19, 2018, 7:38 AM), <https://www.businessinsider.com/new-healthy-fast-food-chains-better-than-mcdonalds-2017-2> (listing ten up-and-coming food chains advertising as healthy, cleaner food options).

⁸¹ Listing of Color Additives Exempt From Certification; Soy Leghemoglobin, 84 Fed. Reg. 37,573, 37,573-74 (Aug. 1, 2019) (to be codified at 21 C.F.R. pt. 73) (explaining that Impossible Foods, Inc. filed and the FDA approved a color additive petition seeking permission for the FDA to consider soy leghemoglobin safe as a color additive, which would allow Impossible Foods to sell raw imitation beef in grocery stores); H. Claire Brown, *After Plant Blood Gets FDA Approval, the Impossible Burger is Set to Hit Supermarket Shelves*, THE NEW FOOD ECON. (July 31, 2019), <https://newfoodeconomy.org/plant-blood-heme-fda-approval-impossible-burger/>.

⁸² Chase Purdy, *Plant-Based Meats Sound Healthy, but They’re Still Processed Foods*, QUARTZ (July 1, 2019), <https://qz.com/1655309/beyond-meat-needs-to-communicate-how-it-makes-its-plant-based-burger>; see Press Release, Scott Gottlieb, Food and Drug Admin. Comm’r, Statement from FDA Commissioner Scott Gottlieb, M.D., on modernizing standards of identity and the use of dairy names for plant-based substitutes (Sept. 27, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-modernizing-standards-identity-and-use-dairy-names>.

⁸³ *Beyond Meat Breaks Down After Consumer Group Warns of Chemicals in Fake Meat*, CNBC (June 21, 2019, 5:37 PM), https://www.cnbc.com/video/2019/06/21/beyond-meat-down-after-consumer-group-warns-of-chemicals-in-fake-meat.html?_source=sharebar%7Ctwitter&par=sharebar (explaining via video one consumer groups concerns about the health claims from plant-based meat producers); see Lydia Mulvany & Deena Shanker, *Why the ‘Bloody’ Impossible Burger Faces Another FDA Hurdle*, BLOOMBERG (Dec. 26, 2018, 3:00 AM), <https://www.bloomberg.com/news/articles/2018-12-26/why-the-bloody-impossible-burger-faces-another-fda-hurdle> (discussing the concerns of interested parties about alternative meat producers’ lack of transparency when applying for FDA approval of “heme,” an additive in Impossible Foods’ plant-based meat).

during laboratory processing; the USDA manages the production and labeling of cell-based meat products developed from livestock and poultry cells; and food companies market the cell-based meat products for sale thereafter.⁸⁴ One recent news article notes that, “[w]hile plant-based meat companies are ultimately making processed foods, their marketing is more in line with natural, organic offerings.”⁸⁵ Indeed, more processing may not equate to being better-for-you, and in fact, some of these “meatless” products have come under attack in recent years due to alleged risks associated with the processing of their products.⁸⁶ For example, a consumer advocacy group, “Moms Across America,” recently attacked Impossible Foods for allegedly high levels of the herbicide glyphosate in the burgers.⁸⁷

The question present in these marketing efforts is whether advertising the very food that the product is replacing is misleading to consumers.⁸⁸ A highly-processed food product by its nature is not grown in the earth, so does it really deserve the title “natural” or “healthy”? In this way, are consumers really getting the bargain for their buck with plant-based foods? In the “Just Mayo” case, the FDA voiced its concerns about misbranding involving Hampton Creek’s advertising mayonnaise with an image of an egg on the label when the product was egg-free.⁸⁹ The issue was why an egg-free product

⁸⁴ See Press Release, U.S. Food & Drug Admin., FDA News Release: USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Mar. 7, 2019), <https://www.fda.gov/news-events/press-announcements/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food-products-cell-lines-livestock-and>.

⁸⁵ Purdy, *supra* note 82.

⁸⁶ Joseph Mercola, *Impossible Burger Attacks Moms for Publishing Pesticide Results*, MERCOLA (June 4, 2019), <https://articles.mercola.com/sites/articles/archive/2019/06/04/impossible-burger-glyphosate-residues.aspx>; Tuttle Dedvukaj, *Plant-based Burgers May Not Be As Healthy As You Think*, FOX BUS. (Aug. 2, 2019), <https://www.foxbusiness.com/personal-finance/plant-based-burgers-may-not-be-as-healthy-as-you-think>.

⁸⁷ Mercola, *supra* note 86; see generally Impossible Foods, Inc., *The Unofficial Correction of “Moms Across America”* (May 18, 2019), https://assets.ctfassets.net/hhv516v5f7sj/77NQsg1qDb6d9Hi4PBQA6y/93b2af7c3f12ce2e4050e03a6e0345e7/Unofficial_Correction_Moms_Across_America_05202019.pdf (responding to the claims of Moms Across America).

⁸⁸ Amelia Lucas, *Plant-Based Eggs Land Their First Major Fast Food Deal*, CNBC (2019), <https://www.cnbc.com/2019/07/25/plant-based-eggs-land-their-first-major-fast-food-deal.html> (explaining that plant-based eggs are now showing up at fast-food establishments); Impossible Foods, Inc., *What Are the Ingredients?* (2019), <https://faq.impossiblefoods.com/hc/en-us/articles/360018937494-What-are-the-ingredients>.

⁸⁹ Letter from Center for Food Safety and Applied Nutrition, U.S. Food & Drug Admin., to Joshua Tetrick, Founder and Chief, Hampton Creek Foods, Inc. (Aug.

has an egg on the picture of the label and whether this was confusing to consumers.⁹⁰ Just Mayo subsequently relabeled its packaging by clarifying that the product was egg-free, and that the product packaging no longer displays an egg.⁹¹ Similarly, Muscle Milk revised its labeling to address allegations that arose in private litigation that its product was misbranded because it did not fit the standard of milk as consumers understood it, as it contained milk protein instead of cow's milk.⁹² These cases demonstrate that consumers should think critically about the advertisements that they perceive related to certain self-care, plant-based products until the FDA determines the meaning of certain terms or decides whether to allow replacement products to advertise the very product that they are substituting.

VI. How Can Manufacturers, Consumers, and the U.S. Federal and State Governments Help?

A. *Manufacturers*

The lack of research, a growing self-care industry, consumers' interest in self-treatment, and the rise of alternative therapies, including food and other ingestible ingredients, strongly suggest that the FDA has wide latitude to regulate in these spaces and should provide guidance to industry stakeholders and education and warnings to consumers. The FDA should also regulate in these food-drug hybrid spaces in the interest of consumers' present and future health. So, what can industry stakeholders do to help ensure that neither legislative nor executive action creates precedent against their interests in this space?

Companies promoting novel products do not always follow the golden rule of advertising,⁹³ especially in the e-commerce

12, 2015), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hampton-creek-foods-08122015>.

⁹⁰ "Just Mayo" Just Isn't Warns FDA, FED'N OF AMERICAN SCIENTISTS, (Sept. 14, 2015, 1:10 PM), <https://fas.org/sgp/crs/misc/mayo.pdf>.

⁹¹ *Just Mayo, Non-GMO, 12 oz*, WALMART (2019), <https://www.walmart.com> (search "Just Mayo" and click on 12-oz offering).

⁹² See generally Andrew Adam Newman, *Got Milk? For Sports Drink Maker, Nestlé Says No*, N.Y. TIMES (July 26, 2009), <https://www.nytimes.com/2009/07/27/business/media/27adco.html>, (giving a brief overview of the petition filed by Nestlé in regards to the labeling of Muscle Milk); see also *Muscle Milk Pro Series 40 Protein Shake, Go Bananas, 14 Oz*, WALMART, <https://www.walmart.com> (search "Muscle Milk Pro Series 40 Protein Shake") (showing the Muscle Milk label as now saying "CONTAINS NO MILK").

⁹³ Federal Trade Commission Act, 15 U.S.C. § 45 (2012) (stating in Section 5 that unfair or deceptive acts or practices in or affecting commerce are prohibited and stating in Section 12 that false advertising that is likely to induce the purchase of foods, drugs, devices, services, or cosmetics is also prohibited).

space.⁹⁴ Sometimes marketers appear to forget that all advertising claims must be truthful, accurate, and not misleading or deceptive.⁹⁵ They continue to push the envelope with even the most basic of claims and marketing tactics. Companies can help combat misleading marketing by not making un- or under-substantiated claims about their products; they can continue to manufacture their products according to current good manufacturing practices (“GMPs”); and they can err on the side of caution when making claims related to human health to avoid misleading consumers about products that various stakeholders (the self-help industry, the government, and consumers) across the country are still getting to know.

The food and beverage, drug, and cosmetics industries have a great opportunity to research the health impacts on the human body of the various alternative therapies and products hitting the market today, to present scientific-based research studies to the FDA and industry stakeholders to substantiate their claims and advertisements, and to advocate for the safest, most effective alternative therapies and products that emerge from their research.⁹⁶ Well-researched health benefits are far more likely to lead to well-founded product claims and advertisements than a blank slate of regulatory fear and inaction.⁹⁷ Hybrid food-drug products thus present enormous opportunity for industry stakeholders to play a role in not only changing law and policy, but also influencing consumers’ perspectives.

Novel consumer goods products present more risk of misleading consumers because they fall into areas of regulatory uncertainty. The FDA’s comfort zones are and have been food, drugs, and cosmetics, but, as hybrid products have emerged, the FDA grows weary of—and at times paralyzed over—how crossover products may interact with each other on the human body and in what amounts.⁹⁸ If consumers do not know what a food or other consumable product is, how can they make an informed choice whether to purchase and ingest it? If the U.S. federal and state governments allow food and other consumable products to be marketed with names that are potentially misleading about what the product is, how can consumers know what is good for them?

⁹⁴ US. FOOD & DRUG ADMIN., VAPEJOOSE LETTER, *supra* note 56.

⁹⁵ *Id.*

⁹⁶ Comment Notice, 74 Fed. Reg. 3059 (Jan. 16, 2009).

⁹⁷ *See id.*

⁹⁸ Presentation at the FDLI Annual Conference: Marijuana, CBD, and Hemp: Understanding the Current Regulatory Landscape and How it Might Change (May 3, 2019).

Plentiful options at grocery and convenience stores already daunt consumers. How much more daunting is grocery shopping when advertisements for CBD and other un- or under-regulated plant-based products line the aisles and counters with less-than-truthful claims enticing consumers to “try” a new product? What should consumers do amid the exploding self-care industry, rising healthcare costs, and unregulated claims pertaining to ingestible self-care products? These questions, of course, may not yet have an answer, but they are worth asking as technology drives consumers toward more food and related self-care options.

B. Consumers

Consumers must remain vigilant in their analysis. They should not stop reading labels, researching product manufacturers, and thinking critically about the print and digital advertising (1) on product packaging and labels and (2) on websites and in social media, respectively. The CBD, Kratom, and plant-based product debates present the lingering question of how much risk it will take to change the law. Will it take a child eating several CBD-infused gummies, or something more or less? Underregulated products like CBD and Kratom pose the risk of food fraud to consumers where the integrity of the product has not yet been proved. Ms. Fritz warns:

Anyone using CBD should make serious inquiries into the quality and purity of the product . . . [S]tudies have shown that many of the CBD oils out there consist mostly of olive oil or another alternative oil besides true CBD. Therefore, consumers should question the quality of the products they elect to purchase and use.⁹⁹

Consumers should be wary of the new ease of click-to-purchase transactions. They should continue to do their homework by consulting multiple reputable sources about such novel self-care products including food and food additives.

⁹⁹ Interview with Koral Fritz, Attorney, Innovative Law Group (July 15, 2019). Ms. Fritz is a licensed attorney practicing in West Michigan. Her current practice focuses on providing guidance to business clients on contracts, real estate, environmental, and litigation matters. Along with a law degree, she also earned her Master’s degree in Food and Agriculture Law and Policy from the Vermont Law School. Her experience ranges from working for national nonprofits on food policy to counseling clients retailing CBD and others interested in growing and marketing cannabis.

C. Government

While the FD&C Act widely covers the regulation of food, drugs, and cosmetics, the FDA has struggled for years with how to regulate hybrid products that straddle two or more of these categories. The best, most illustrative example of an opportunity for industry stakeholders to influence U.S. food and drug law currently rests with the debate over hemp and hemp-derived products since the Farm Bill of 2018.¹⁰⁰ This area is ripe for stakeholder discussion and thought leadership because of manufacturers' ability to create products that contain various parts of the plant at varying levels.

Examples are plentiful of manufacturers using CBD as an ingredient in their food products, dietary supplements, and drugs.¹⁰¹ Examples include CBD-infused gummies, dietary supplements containing CBD, topical creams and oils containing CBD, CBD-infused nasal sprays, CBD brownies and cookies, etc.¹⁰² The same is true with Kratom. Due to its powder-like form, Kratom can easily be added to other products.¹⁰³ There is no better time to impact U.S. food and drug law than now with the rise of these spaces adjacent to typical food products and dietary supplements. The FDA is begging the industry to take charge with science-based evidence to demonstrate substantiated risks and benefits before the FDA will take a position on CBD, Kratom, and other plant-based ingredients in food products, dietary supplements, and consumer goods that dip into both worlds.¹⁰⁴ As in the case of CBD, influencing U.S. food and drug law is not that difficult. The FDA comment process is all inclusive and inviting.

However, government indecision has contributed to marketplace and consumer confusion over CBD.¹⁰⁵ Medical doctor Peter Grinspoon explains that “the government’s position on CBD is

¹⁰⁰ See Amy Abernethy & Lowell Schiller, *FDA Is Committed to Sound, Science-Based Policy on CBD*, FOOD & DRUG ADMIN. (July 7, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>.

¹⁰¹ There are currently over 9,000 “Health & Household” items listed for sale on Amazon containing CBD. See AMAZON, <https://www.amazon.com/> (type “CBD” in search bar; then narrow search results to “Health & Household” under “Department”) (last visited Nov. 10, 2019).

¹⁰² *Id.*

¹⁰³ Lileana Pearson, *Dietary Substitute Kratom Stays in Legal Gray Area*, WWOT NBC 6 OMAHA (July 17, 2019, 5:27 PM), <https://www.wowt.com/content/news/Dietary-substitute-Kratom-stays-in-legal-gray-area-512854091.html>.

¹⁰⁴ See U.S. FOOD & DRUG ADMIN., FDA REGULATION OF CANNABIS, *supra* note 43.

¹⁰⁵ See Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90194, 90194–96 (Dec. 14, 2016) (responding to public comments of confusion on the legality of CBD when not combined with cannabinoids).

confusing, and depends in part on whether the CBD comes from hemp or marijuana.”¹⁰⁶ The wide disparity in how law firms and other legal and compliance professionals and stakeholders position information about the Farm Bills of 2014 and 2018 and their effect on hemp and CBD further demonstrates the likelihood for consumer confusion. Attorney Koral Fritz explains:

The recent popularity of CBD has forced the FDA to play catch up. As often happens, the market is ahead of the law . . . [T]he new supply and demand for these products has led to the FDA holding hearings with industry stakeholders to develop a regulatory framework for CBD . . . [M]onths ago[,] the FDA reiterated the clear position that CBD is not approved for use in food, however, the agency basically told the market that it will not be focusing on enforcement except for when a CBD product bares a health claim that goes too far. The FDA seems the most concerned currently with any CBD product making a qualified health claim. The FDA has taken enforcement action against companies that make unfounded, egregious claims about their products' ability to limit, treat, or cure cancer or diseases.¹⁰⁷

The FDA has made decisions on hemp seed, hemp oil, and hemp protein.¹⁰⁸ However, the path forward for the cannabis and hemp industries depends on the USDA's and the FDA's ongoing efforts to issue guidance and rules for implementation of the 2018 Farm Bill.

Despite the need for FDA guidance with input from the industry on CBD, Kratom, and other emerging plant-based products, the FDA could also launch an education campaign to warn consumers about the dangers of ingesting these products that still lack research and regulation.¹⁰⁹ While the FDA continues to

¹⁰⁶ Peter Grinspoon, *Cannabidiol (CBD) – What We Know And What We Don't*, HARVARD HEALTH BLOG (Aug. 24, 2018, 6:30 AM), <https://www.health.harvard.edu/blog/cannabidiol-cbd-what-we-know-and-what-we-dont-2018082414476>.

¹⁰⁷ Interview with Koral Fritz, *supra* note 99.

¹⁰⁸ U.S. FOOD & DRUG ADMIN., FDA RESPONDS TO THREE GRAS NOTICES FOR HEMP SEED-DERIVED INGREDIENTS FOR USE IN HUMAN FOOD (Dec. 20, 2018), <https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notice-hemp-seed-derived-ingredients-use-human-food>.

¹⁰⁹ To the FDA's credit, the FDA has issued several public statements about CBD, warning consumers about its potential effects and promising an industry update in the near future. See Abernethy & Schiller, *supra* note 100.

determine the health risks involved with these types of products, FDA warnings and educational messages could help consumers think critically about these products before ingesting them. FDA public statements are helpful, but the FDA should more closely meet consumers where they are—in the marketplace—to help ensure that they understand the health risks of not only the plant-based food additives discussed in this paper, but also those yet to come.

VII. Conclusion

The self-care industry will not slow down to accommodate for regulatory concern, consumer confusion, or manufacturers' perfection of their products or processes. The unknown or misunderstood lurking health risks associated with products containing un-regulated or under-regulated ingredients will require a village rather than a single government or consumer advocacy group to help shield consumers from deceptive advertisements. Where the marketplace has revealed consumers' interests, it has also exposed the need for increased scrutiny from industry, the public, and government to help ensure that risks to human health are minimal as such self-care products come available for sale.

Industry influence is at an incredible high to shape the U.S. legal and regulatory framework for food and drug policy in the self-care space. The bright spot remains the industry's opportunity to influence how the U.S. federal and state governments decide to regulate the products that entice consumers due to their potential therapeutic effects as well as consumers' ability to experience managing their own health. The FDA and consumers are listening as well, and each party has a significant role to play. By each stating and justifying their interests and through their collaborative efforts, the three actors can help the U.S. expedite its journey towards increased government regulation that fits both the industry's and consumers' appetites for guidance while remaining flexible enough to allow for innovative self-care food products and food additives to develop for years to come.