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CBD and Gluten-Free: Compliance Challenges and Regulatory Action in New Areas of Food and Drug Law

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CBD AND GLUTEN-FREE: COMPLIANCE CHALLENGES AND REGULATORY ACTION IN NEW AREAS OF FOOD AND DRUG LAW

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This Article examines the challenges of regulating new areas of food and drug law and promoting industry compliance by considering two case studies: the U.S. regulation of cannabidiol (CBD) products and that of gluten-free items. Gluten-free claims on packaged foods have been subject to a set of U.S. Food and Drug Administration rules since those rules became effective in 2014. This new regulatory standard has improved the ability of consumers who need to rely on gluten-free labeling for health reasons to do so. Some concerns remain, however, about the mislabeling of foods that legally cannot be termed as gluten-free based on the ingredients they contain, as well as the gluten-free labeling of foods whose gluten levels exceed legal limits. CBD items are another set of novel products that present regulatory and enforcement challenges with respect to the protection of consumer health and safety. Although the FDA has sent warning letters to many companies selling CBD products that impermissibly claim to treat serious diseases, the widespread sale and marketing of CBD products bearing such claims continues.

This Article uses the two case studies described above to explore industry compliance best practices and recommendations for regulatory action in evolving and emerging product areas. It further considers how companies manufacturing, selling, or marketing novel products may anticipate and react to changing law, or conform their operations to existing sets of rules that have the greatest application to their products. This Article also examines how consumer welfare may be best promoted through regulatory action and response. A more robust agency enforcement strategy is warranted with respect to both CBD products and gluten-free labeled items in order to better allow consumers to trust that these types of products on the marketplace fully comply with agency standards. Such increased enforcement would promote and more completely fulfill the purpose of long-existing agency rules, such as those concerning unsupported health claims, or more recent ones, such as the permitted ingredients or quantities of gluten in packaged food items labeled as gluten-free.

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INTRODUCTION

Products containing cannabidiol (CBD) and packaged food items bearing gluten-free labels both present novel challenges to the work of the U.S. Food and Drug Administration (FDA), as well as to industry actors seeking to understand and ensure their compliance with relevant regulations. Consumer interest in and purchasing of each of these types of products has greatly increased in recent years. For gluten-free products, this is, in part, due to the increased recognition of the incidence of celiac disease in the United States. For CBD items, this has occurred, in part, due to legislative changes allowing for the more widespread use of CBD in some types of consumer products. The rising popularity of each type of product presents a challenge to the FDA with respect to ensuring the protection of consumer health and safety. The

agency is responsible for policing the claims these products carry, as well as confirming that the composition of each of these types of products adheres to legal standards.

These two types of novel products, and the regulatory challenges that accompany them, also pose compliance challenges for their manufacturers and sellers. Companies must ensure that they have identified all applicable standards and regulations, understand their full set of compliance responsibilities, and take all necessary measures to incorporate those standards with respect to product composition and quality, marketing, packaging, and other areas. Companies selling fully compliant products must somehow signal the quality of their products to consumers in a crowded marketplace where agency enforcement may not be robust enough to prevent their competitors from selling non-compliant products. Consumer welfare is also at issue where consumers cannot reliably assume that products on the market are safe and conform to regulatory standards by virtue of their continued presence on the marketplace without agency intervention.

Since regulations governing gluten-free claims appearing on packaged foods became effective in 2014, a numerical threshold has governed the permitted level of gluten in such foods.[1] These regulations have also set parameters concerning ingredients that may be used in packaged food items bearing such claims. CBD products, like other items subject to FDA regulation, are governed by long-standing FDA rules regarding unproven statements claiming that the products treat diseases. The level of compliance for each type of product is markedly different, despite the similarities of clear regulatory rules applicable to each type of item. Namely, the presence of applicable regulatory rules has proven largely insufficient to ensure the self-policing of products by manufacturers and sellers of CBD products. In contrast, broad (but not complete) compliance exists with respect to items labeled as gluten-free, despite the lack of extensive agency enforcement. This Article considers the reasons for this disparity in assessing the extent of compliance of each product type to regulatory standards.

Finally, this Article examines how these two case studies of novel product types, agency response, and industry compliance may inform a consideration of the regulation of novel product types more generally. These examples also illustrate issues of regulatory standard-setting, agency enforcement, and industry compliance for new categories of products subject to U.S. regulation.

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1. *Gluten and Food Labeling*, U.S. FOOD & DRUG ADMIN. (Aug. 5, 2013), https://www.fda.gov/food/nutrition-education-resources-materials/gluten-and-food-labeling [https://perma.cc/7DRX-9BCX].

I. CBD PRODUCTS

A. History and Nature of CBD

CBD, short for cannabidiol, is "a non-psychotropic plant constituent" that "is generally found in relatively high concentrations in Cannabis."[2] CBD "is derived from the *Cannabis sativa* plant (commonly referred to as cannabis), which includes both marijuana and hemp."[3] CBD "does not cause marijuana-like effects," but "has been shown to produce a plethora of pharmacological effects, many of them associated with both central and peripheral actions."[4] CBD is distinct from tetrahydrocannabinol, or THC, which is "the chief intoxicant in marijuana".[5] "[E]xperimental research indicates that CBD is not associated with abuse potential."[6] CBD was first isolated by Roger Adams, who in 1940 applied for a patent for several isolation processes (which was granted in 1942).[7] "The structures and stereochemistry of CBD . . . were elucidated in Raphael Mechoulam's laboratory: in 1963 for CBD."[8] Dr. Mechoulam's lab was also the first to synthesize a form of CBD in 1965.[9]

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2. Raphael Mechoulam et al., *Cannabidiol – Recent Advances*, 4 CHEMISTRY & BIODIVERSITY 1678, 1679 (2007).

3. Agata Dabrowska & Renée Johnson, *FDA Regulation of Cannabidiol (CBD) Consumer Products*, CONGRESSIONAL RESEARCH SERVICE (Feb. 10, 2020), https://crsreports.congress.gov/product/pdf/IF/IF11250. Further, "*[c]annabis sativa* is usually called 'hemp' when used as a source of fiber, 'hempseed' when used as a source of seed oil, and 'marijuana' . . . when used for euphoric inebriants and therapeutic drugs. 'Industrial hemp' refers to non-narcotic cultivars of the crop grown for fiber or oil, usually licensed for these purposes." Ernest Small, *Evolution and Classification of* Cannabis sativa *(Marijuana, Hemp) in Relation to Human Utilization*, 81 BOT. REV. 189, 191 (2015).

4. Mechoulam et al., *supra* note 2, at 1679.

5. *THC*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/THC [https://perma.cc/P66S-QJFJ].

6. Expert Committee on Drug Dependence, *Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2*, WORLD HEALTH ORGANIZATION [WHO] 1, 14 (2017), https://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf [https://perma.cc/B3M4-W8S9]. Moreover, CBD "is not thought to be psychotropic and has a different side effect profile compared to THC. . . . Based on current data and testing methodologies, patients are not likely to get high on purified, CBD-only formulations[,]" but "there are many sources of CBD that are available to patients due to various state approvals for CBD, THC, and marijuana for medicinal and recreational purposes. Some of these formulations can be verified as pure CBD, while others may contain other cannabinoids such as THC that may change the abuse potential for that particular product." Angela Birnbaum, *How High Can Patients Get on CBD?*, 19(6) EPILEPSY CURRENTS 382, 383 (2019).

7. Isolation of Cannabidiol, U.S. Patent No. 2,304,669 (filed Aug. 16, 1940) (issued Dec. 8, 1942).

8. Roger G. Pertwee, *Cannabinoid Pharmacology: The First 66 years*, 147 BRIT. J. PHARMACOLOGY S163, S163 (2006).

9. *Id.*

CBD has been shown in clinical trials "as an effective treatment for at least some forms of epilepsy."[10] In 2018, the FDA approved a drug, Epidiolex, which "contains a purified drug substance derived from marijuana[,]" in this case, CBD, "for the treatment of seizures associated with two rare and severe forms of epilepsy."[11] The FDA also later approved Epidiolex "for the treatment of seizures associated with tuberous sclerosis complex."[12] At the time this Article was written, Epidiolex remained the only FDA-approved prescription CBD product.[13]

"There is also evidence that CBD may be a useful treatment for a number of other medical conditions[,]" but "this research is considerably less advanced than for [the] treatment of epilepsy."[14] It has been suggested that CBD might have effects in the context of a variety of diseases.[15] CBD might also be beneficial for cannabis and tobacco addiction treatment.[16] Project CBD was established in 2009, and is "dedicated to promoting and publicizing research into the medical uses of cannabidiol (CBD) and other components of the cannabis plant."[17] It set up a website in 2010 listing CBD studies "organized by disease or condition."[18]

CBD may appear in a variety of products, such as foods and beverages; supplements; lotions, creams, and other body care products; vape cartridges; and even pet care items.[19] In practice, CBD products may also contain THC in varying amounts, despite the legal limits on the quantity of THC that legally-marketed CBD products may contain (discussed in greater detail in Section I.B.1. of this Article).[20]

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10. *Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2*, *supra* note 6, at 15.

11. News Release, U.S. Food and Drug Administration, *FDA Approves First Drug Comprised of an Active Ingredient Derived from Marijuana to Treat Rare, Severe Forms of Epilepsy* (June 25, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms [https://perma.cc/9SCG-PYFM].

12. News Release, U.S. Food and Drug Administration, *FDA Approves New Indication for Drug Containing an Active Ingredient Derived from Cannabis to Treat Seizures in Rare Genetic Disease* (July 31, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-new-indication-drug-containing-active-ingredient-derived-cannabis-treat-seizures-rare.

13. EPIDIOLEX, https://www.epidiolex.com [https://perma.cc/D3HU-5NJ4].

14. *Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2*, *supra* note 6, at 17.

15. *Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2*, *supra* note 6, at 18.

16. *Cannabidiol (CBD) Pre-Review Report Agenda Item 5.2*, *supra* note 6, at 17.

17. *About Project CBD*, PROJECT CBD, https://www.projectcbd.org/about-pcbd.

18. Amanda Chicago Lewis, *A Hidden Origin Story of the CBD Craze*, N.Y. TIMES (May 23, 2020), https://www.nytimes.com/2020/05/23/sunday-review/coronavirus-cbd-oil.html [https://perma.cc/W9XL-9VSZ].

19. *52 CBD Products on the Market*, MINISTRY OF HEMP (Apr. 22, 2021), https://ministryofhemp.com/blog/cbd-products-list/ [https://perma.cc/34AY-4PS7].

20. *Infra* Section I.B.1.; *See also* Nsikan Akpan & Jamie Leventhal, *Is CBD Legal? Here's What You Need to Know, According to Science*, PBS NEWS HOUR (July 12, 2019, 5:04

Combined CBD sales in the U.S. were estimated by the *Hemp Business Journal* to amount to $534 million in 2018, up five times from a reported $108 million in 2014.[21] It has been estimated that U.S. sales of CBD will "exceed $1 billion in 2020 and . . . reach nearly $2 billion in 2022[,]" divided about evenly among the three markets of hemp-derived CBD, marijuana-derived CBD, and pharmaceutical CBD (namely, Epidiolex).[22]

One major industry group is the U.S. Hemp Roundtable, which "is a coalition of dozens of leading companies and organizations committed to safe hemp and CBD products," and provides information to industry groups and citizens about the current legal status of hemp and CBD.[23] Others include the Cannabinoid Industry Association and the National Cannabis Industry Association.[24]

B. CBD Regulation and Enforcement in the United States

1. Federal

As CBD is generally derived either from marijuana or from hemp, it has historically been illegal or restricted within the United States.[25] The Marihuana Tax Act of 1937 imposed a tax on transfers of marijuana.[26] The Act made "hemp importation and commercial production in [the U.S.] . . . less economical[;]" as a result, "[s]cientific research and medical testing of marijuana also virtually disappeared."[27] The Controlled Substances Act was enacted in 1970 and formally banned cannabis plants.[28] The U.S. Drug Enforcement Administration (DEA) "made clear" by its conduct that it viewed the cultivation of cannabis sativa plants to produce industrial products "as unlawful under the federal criminal statutes governing marijuana."[29] Presently,

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PM), https://www.pbs.org/newshour/science/is-cbd-legal-heres-what-you-need-to-know-according-to-science [https://perma.cc/G8B2-SE6U].

21. Dabrowska & Johnson, *supra* note 3.

22. Dabrowska & Johnson, *supra* note 3.

23. *Who We Are*, U.S. HEMP ROUNDTABLE, https://hempsupporter.com/about [https://perma.cc/HE5K-VDZ9].

24. *About*, CANNABINOID INDUSTRY ASSOCIATION, https://cbdindustryassociation.org/about/ [https://perma.cc/M7RQ-57D6]; *About Us*, NATIONAL CANNABIS INDUSTRY ASSOCIATION, https://thecannabisindustry.org/about-us/ [https://perma.cc/AB5A-G6L8].

25. Akpan & Leventhal, *supra* note 20.

26. Leary v. United States, 395 U.S. 6, 23-24 (1969); John Hudak, *The Farm Bill, Hemp Legalization and the Status of CBD: An Explainer*, BROOKINGS (Dec. 14, 2018), https://www.brookings.edu/blog/fixgov/2018/12/14/the-farm-bill-hemp-and-cbd-explainer/ [https://perma.cc/7XFC-37G6].

27. *Did You Know... Marijuana Was Once a Legal Cross-Border Import?*, U.S. CUSTOMS AND BORDER PROTECTION, (Dec. 20, 2019) https://www.cbp.gov/about/history/did-you-know/marijuana/ [https://perma.cc/8LT7-FLK2].

28. Controlled Substances Act, 21 U.S.C. §§ 801-966; Hudak, *supra* note 26.

29. N.H. Hemp Council, Inc. v. Marshall, 203 F.3d 1, 5 (1st Cir. 2000).

"[m]arijuana is a Schedule I controlled substance under the Controlled Substances Act . . . and is regulated by the Drug Enforcement Administration (DEA)."[30] "The unauthorized manufacture, distribution, dispensation, and possession of marijuana is prohibited."[31]

The 2018 Farm Bill "removed hemp, defined as cannabis (*Cannabis sativa L.*) and derivatives of cannabis with extremely low concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC) (no more than 0.3 percent THC on a dry weight basis), from the definition of marijuana in the Controlled Substances Act (CSA)."[32] Thus, pursuant to the 2018 Farm Bill, CBD products with less than 0.3% THC have been decriminalized and are therefore no longer subject to the jurisdiction of the Drug Enforcement Administration (DEA).[33] Purified CBD from hemp plants is legal under federal law, while that from marijuana plants remains illegal.[34] The 2018 Farm Bill also "allows states and tribes to submit a plan and apply for primary regulatory authority over the production of hemp in their state or in their tribal territory."[35]

The FDA retains authority over hemp products to the extent that such products fall within FDA-regulated categories of foods, dietary supplements, human and veterinary drugs, and cosmetics.[36] Unapproved new drugs may violate Sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 21 U.S.C. 355(a) and 331(d), and can also be considered misbranded drugs under 21 U.S.C. 352(f)(1).[37] Introducing or delivering such unapproved new drugs or misbranded drugs into interstate commerce violates the

30. Agata Dabrowska & Renée Johnson, *FDA Regulation of Cannabididol (CBD) Products*, CONGRESSIONAL RESEARCH SERVICE, (June 12, 2019), https://fas.org/sgp/crs/misc/IF11250.pdf [https://perma.cc/E4PU-M7DU]. Recent DEA standards mandating that THC levels not exceed a 0.3 THC limit raised concerns about the potential for DEA enforcement against unfinished CBD products based on their THC levels. Barak Cohen & Tommy Tobin, *New DEA Rule May Threaten CBD Manufacturing*, PERKINS COIE: FOOD LITIGATION NEWS (Aug. 27, 2020), https://www.foodlitigationnews.com/2020/08/new-dea-rule-may-threaten-cbd-manufacturing/ [https://perma.cc/VPK6-SUAK]. This Article, however, focuses on agency enforcement against CBD products by the FDA based on health claims, and so DEA enforcement policy is not discussed in depth.

31. Dabrowska & Johnson, *supra* note 30.

32. *Hemp Production and the 2018 Farm Bill: Hearing Before the S. Comm. on Agric., Nutrition, & Forestry*, 116th Cong. 47 (2019) (statement of Amy Abernethy, Principal Deputy Comm'r Food & Drug Admin. Dep't Health & Hum. Servs.).

33. Akpan & Leventhal, *supra* note 20.

34. Akpan & Leventhal, *supra* note 20.

35. *State Industrial Hemp Statutes*, NAT'L CONF. STATE LEG. (Apr. 16, 2020), https://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx [https://perma.cc/Q7TV-DCCM].

36. Statement of Amy Abernethy, *supra* note 32, at 47-48.

37. Warning Letter to Infinite Product Company LLLP DBA Infinite CBD, U.S. FOOD & DRUG ADMIN. (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/infinite-product-company-lllp-dba-infinite-cbd-593175-11222019[https://perma.cc/X7PC-EAW7].

FD&C Act.[38] CBD products are excluded from the dietary supplement definition under 21 U.S.C. 321(ff)(3)(B)(i) and (ii), and therefore cannot be labeled as dietary supplements.[39] In September 2020, a bill was introduced in the U.S. House of Representatives that would allow CBD and any other ingredient derived from hemp to be lawfully used as a dietary ingredient in a dietary supplement, notwithstanding the existing prohibitions of the FD&C Act.[40]

Any substance intentionally added to food as a food additive is subject to premarket review and approval unless the food substance "is generally recognized, among qualified experts, as having been adequately shown to be safe under . . . its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive."[41] "[S]ection 201(s) of the FD&C Act provides two alternatives for general recognition of safety — through scientific procedures, or through experience based on common use in food."[42] Per the FDA, "[a] conclusion of GRAS status must be based on the totality of the publicly available and corroborative evidence about the safety of the substance under the conditions of its intended use, including both favorable and potentially unfavorable information."[43] CBD is considered to be an unsafe food additive, and foods with CBD added are considered adulterated under 21 U.S.C. 342(a)(2)(C)(i); it is illegal to introduce such products into interstate commerce pursuant to 21 U.S.C. 331(a).[44]

2. *State*

In addition to federal regulations, state laws and regulations may also apply to the sale and marketing of CBD products; the requirements of these provisions can vary widely between jurisdictions.[45] States have also pursued actions to enforce their regulations concerning CBD and their broader consumer protection laws. For example, in

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38. *Id.*

39. *Warning Letter to Bella Rose Labs*, U.S. FOOD & DRUG ADMIN. (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bella-rose-labs-594246-11222019 [https://perma.cc/52E6-HZXR].

40. H.R. 8179, 116th Cong. (2020).

41. *Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN. (Sept. 6, 2019), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.

42. U.S. FOOD & DRUG ADMIN., CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *Regulatory Framework for Substances Intended for Use in Human Food or Animal Food on the Basis of Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug and Cosmetic Act: Guidance for Industry* 18 (2017), https://www.fda.gov/media/109117/download [https://perma.cc/XK6R-7FNW].

43. *Id.* at 20.

44. *See, e.g.*, U.S. Food & Drug Admin., Warning Letter to Natural Native LLC (Nov. 22, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/natural-native-llc-593385-11222019 [https://perma.cc/7JFJ-NY2Y].

45. *See* Bruce Barcott, *Is CBD Legal in Your State? Check This Chart to Find* Out, LEAFLY (Nov. 22, 2019), https://www.leafly.com/news/cbd/is-cbd-legal-state [https://perma.cc/D3G6-BJ36].

April 2020, the New York State Office of the Attorney General issued a cease and desist letter to the seller of a product that claimed to treat COVID-19.[46] Similarly, the Oregon Attorney General's Office ordered a CBD store to take down advertising "claiming their products could boost immunity" against COVID-19, based on its violation of Oregon's Unlawful Trade Practices Act and state law "requir[ing] scientific evidence to support promotional health claims."[47] In 2019, the South Dakota Attorney General issued a statement clarifying that all forms of CBD oil were still illegal within that state under state law (with the exception of Epidiolex, which the state regulated as a controlled substance).[48]

C. CBD-Specific Issues in Regulation and Product Marketing

The complicated legal landscape surrounding CBD products poses a significant challenge to CBD manufacturers, marketers, and sellers seeking to understand their legal responsibilities. In an uncertain legal or regulatory environment, retailers and manufacturers must face challenges in ensuring that they have continued access to the marketplace as well as other resources they need to transact business, such as the banking system. Such risks, of course, are greatest where the legality of a product itself might be at issue or has historically been so, as has been the case for CBD and other hemp-derived substances.

Understanding the interaction between and the effect of applicable state and federal legal provisions can pose a significant challenge for actors within the CBD industry. One attorney noted, prior to the 2018 Farm Bill, that:

> [t]he conflict between federal and state laws on the medical use of cannabis products, the lack of consistency among state laws, and the availability of artisanal cannabis and CBD products in dispensaries and online has caused significant confusion for researchers, practitioners, and patients and their caregivers, particularly with regard to CBD products.[49]

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46. N.Y. Off. of the Att'y Gen., *Cease and Desist Notification to Finest Herbalist* (Apr. 1, 2020), https://ag.ny.gov/sites/default/files/letter_from_ny_attorney_general_to_finest_herbalist.pdf; *see also Pure Herbal Total Defense Immunity Blend*, TRUTH IN ADVERTISING.ORG (Mar. 18, 2020), https://www.truthinadvertising.org/pure-herbal-total-defense-immunity-blend/ [https://perma.cc/AH8N-6AJY].

47. Mila Mimica, *Attorney General Forces Portland CBD Store to Take Down Misleading COVID-19 Advertising*, KGW8 (Mar. 18, 2020), https://www.kgw.com/article/news/health/coronavirus/oregon-attorney-general-coronavirus-cbd-store-claims-covid-19-immunity/283-f2d6abbc-2f02-439b-8e36-310b2aa03ea7 [https://perma.cc/4EG3-NAWG].

48. *Attorney General Ravnsborg Clarifies Questions Regarding Industrial Hemp and CBD (Cannabidiol) Oil*, S.D. OFF. ATT'Y GEN. (Mar. 25, 2019), https://atg.sd.gov/OurOffice/Media/pressreleasesdetail.aspx?id=2167 [https://perma.cc/4JK4-4VUT].

49. *See* Alice Mead, *The legal status of cannabis (marijuana) and cannabidiol (CBD) under U.S. law*, 70 EPILEPSY & BEHAV. 288, 291 (2017).

Even after the passage of the 2018 Farm Bill, some attorneys contended that "CBD companies are still faced with a regulatory quagmire, struggling to understand how to legally promote, label, and distribute CBD consumables in light of the FDA gridlock, inconsistent state laws, and uncertainty as to which pathway will result in a viable resolution."[50]

Confusion about the state of the law on the part of related industry players can also raise challenges for CBD sellers. For example, access to popular marketplaces can become unavailable as those marketplaces seek to protect themselves from liability. Amazon's seller policy prohibits "[l]istings for products containing cannabidiol (CBD) ...including but not limited to: full spectrum hemp oil, rich hemp oil, and products that have been identified as containing CBD by LegitScript[,]" which is a platform performing a variety of merchant and platform monitoring and certification services.[51]

Payment can present another challenge with respect to sales of CBD products. In 2019, Thrive Market stopped selling hemp and CBD products after its merchant processor sent it a notice demanding that Thrive cease the sale of hemp and CBD products.[52] In addition, the payment processor Stripe ended its relationship with the U.S. Hemp Authority as a client in 2019.[53] Sometimes, however, restrictions may ease as legal requirements become better understood. For example, the payment processor Square began allowing CBD merchants to use its payment processing services in late 2019.[54] Square allows sellers

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50. Stephanie Jill Fogel et al., *The CBD Problem: Searching for a Legal Pathway for CBD in Foods and Supplements*, DLA PIPER: PRODUCT LIABILITY ALERT (Sept. 20, 2019), https://www.dlapiper.com/en/us/insights/publications/2019/09/the-cbd-problem/ [https://perma.cc/LBT2-CLRT].

51. *Drugs & Drug Paraphernalia*, AMAZON SELLER CEN. (Oct. 14, 2020), https://sellercentral.amazon.com/gp/help/external/200164490 [https://perma.cc/2PX9-ELDV]; *see also About LegitScript*, LEGITSCRIPT, https://www.legitscript.com/about/ [https://perma.cc/C2N9-4MUS]. Despite this official policy, however, some CBD sellers continue to use the Amazon platform. A Washington Post investigation concluded that eleven of the thirteen items purchased by the Post from Amazon in late 2019 contained CBD; one of the purchased products also contained THC. *See* Jay Greene, *Amazon Prohibits CBD Sales, but It's Still Easy to Buy on the Site*, WASHINGTON POST (Dec. 19, 2019), https://www.washingtonpost.com/technology/2019/12/19/amazon-prohibits-cbd-sales-its-still-easy-buy-site/ [https://perma.cc/BXN8-LSCX].

52. Alicia Wallace, *Thrive Market, an Online Retailer, Is Forced to Stop Selling CBD*, CNN BUS. (June 19, 2019), https://www.cnn.com/2019/06/19/business/thrive-market-cbd/index.html [https://perma.cc/T7SU-6UQQ]; Nick Green, *Update on Our Hemp & CBD Products*, THRIVE MARKET: WELL-BEING BLOG (June 17, 2019), https://thrivemarket.com/blog/update-on-our-hemp-cbd-products [https://perma.cc/9S75-N84W].

53. Wallace, *supra* note 52.

54. Emily Bary, *Square to Begin Payment Processing Program for CBD Sellers*, MARKETWATCH (Oct. 7, 2019, 6:56 AM), https://www.marketwatch.com/story/square-to-begin-payment-processing-program-for-cbd-sellers-2019-10-03; *You Can Now Sell CBD Products with Square*, SQUARE (Oct. 3, 2019), https://squareup.com/us/en/townsquare/sell-cbd-products-square [https://perma.cc/E2NB-RYQS].

"to accept payments for hemp and hemp-derived CBD products that have less than, or equal to, 0.3% THC in most states within the United States," and requires that products be sold in compliance with relevant laws including state laws and the 2018 Farm Bill.[55]

Advertising can also be a challenge for CBD sellers. Twitter's rules specify restrictions on advertising topical CBD products, including, among others, pre-authorization by Twitter; promoting non-ingestible CBD products only; not targeting certain states, including Georgia, Idaho, Iowa, Mississippi, Missouri, Nebraska, Oklahoma, South Dakota, and Virginia; and not targeting users under twenty-one.[56]

D. Agency Enforcement with Respect to CBD Products

Federal enforcement of existing restrictions on CBD products is based on several issues. A threshold issue with respect to agency enforcement is that items marketed as CBD products might, in fact, contain no CBD at all. One commenter noted that the "CBD industry promises a miracle drug but is often selling a placebo: cannabidiol products with zero cannabidiol inside."[57] The FDA notes on its website that some CBD products tested by the FDA were "found to not contain the levels of CBD they claimed to contain."[58] Similarly, a recent industry study of 40 CBD edible products found that 63% contained more CBD than stated on the label.[59] Products might also contain levels of THC in excess of the permitted 0.3%.[60]

Several studies by the FDA confirm the presence of these particular issues with respect to CBD products. Between 2014 and 2018, before the passage of the 2018 Farm Bill, the FDA conducted a testing study of 78 CBD products, selecting them on the basis of products that made serious disease claims, were produced or sold in several states, were

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55. *Square CBD Early Access Program FAQs*, SQUARE, https://squareup.com/help/us/en/article/6821-square-cbd-early-access-program-faqs [https://perma.cc/8D96-ACY5].

56. *Drugs and Drug Paraphernalia*, TWITTER, https://business.twitter.com/en/help/ads-policies/ads-content-policies/drugs-and-drug-paraphernalia.html [https://perma.cc/XGX4-L7GK]; *see also* Griffen Thorne, *Social Media Bans on CBD Ads Make No Sense*, HARRIS BRICKEN: CANNA L. BLOG (Dec. 13, 2019), https://harrisbricken.com/cannalawblog/social-media-bans-on-cbd-ads-make-no-sense/ [https://perma.cc/H7DV-9GPE].

57. Lewis, *supra* note 18.

58. *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2021), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products [https://perma.cc/5LU4-FYF6].

59. *CBD Edibles Market Report: Only 1 in 4 CBD Edibles Contain the Labeled Amount of CBD; 63% of Edibles Contained More CBD than Advertised*, CANNABINOID INDUS. ASS'N, https://cbdindustryassociation.org/cbd-edibles-market-report-only-1-in-4-cbd-edibles-contain-the-labeled-amount-of-cbd-63-of-edibles-contained-more-cbd-than-advertised/ [https://perma.cc/SNJ5-N4SD].

60. Bill J. Gurly, *Content versus Label Claims in Cannabidiol (CBD)-Containing Products Obtained from Commercial Outlets in the State of Mississippi*, TAYLOR & FRANCIS (May 20, 2020), https://www.tandfonline.com/doi/abs/10.1080/19390211.2020.1766634 [https://perma.cc/7SEQ-HNE7].

available for online purchase, or were the basis for consumer complaints or adverse test results.[61] Eighty-six percent of the products tested were found to contain CBD; two were referred to the DEA due to the presence of controlled substances (THC in one and a synthetic cannabinoid in the other).[62] Of the 23 products tested in 2014, only 35% contained levels of CBD consistent with the quantities stated on their labeling.[63] In 2019, the FDA tested 34 CBD products, also selected based on risk factors, and was able to obtain results for 31 with respect to cannabinoids.[64] Of those products that specified the amount of CBD in the product, only 33% contained CBD within 20% of the amount indicated; for those that did not indicate the quantity of CBD, 40% did not contain CBD. In 2020, the FDA tested 147 CBD products, and found that 94% contained CBD.[65] The FDA expects to complete further testing on "a representative, random sample of the current CBD product marketplace[,]" and to "randomly sample products across brands, product categories, and distribution channels, while favoring products with a higher market share."[66] Testing will be completed for "a quantitative determination of total CBD, total THC, and the elements As, Cd, Hg, and Pb."[67]

Another basic issue for regulators is the presence of CBD-infused foods and beverages on the marketplace despite the fact that such products are considered adulterated and therefore not suitable for sale in interstate commerce. Despite the present prohibition against such products sold in interstate commerce, CBD foods and beverages are widely available for purchase online and elsewhere.[68]

Beyond these issues, this Article focuses on the issue of CBD sellers making unsubstantiated claims that their CBD products can be used to treat serious diseases. CBD products have been touted as treatment

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61. *Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations, Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent that Products are Mislabeled or Adulterated,* U.S. FOOD & DRUG ADMIN. 2-3 (2020), https://hempindustrydaily.com/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf [https://perma.cc/4UQ6-5HND].

62. *Id.* at 3.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.* at 7.

67. *Id.* at 8.

68. *See, e.g.*, Maya McDowell, *All the CBD Products You'll Want to Try ASAP,* DELISH (May 28, 2020), https://www.delish.com/food-news/g26934040/cbd-food-products/ [https://perma.cc/Z8HC-TGZF] (characterizing CBD-infused foods and beverages as "[o]ne of the top food trends of this year," and stating that "[t]here are plenty of CBD-infused food and beverage products online[,]" with an accompanying photo gallery of twelve CBD-infused food and drink products, including sparkling water, cereal, popcorn, and candy).

for various illnesses, presenting an enforcement challenge for U.S. regulators at the FDA. As the Principal Deputy Commissioner of Food and Drugs has commented:

> [t]he passage of the 2018 Farm Bill has led to the misperception that all products made from or containing hemp, including those made with CBD, are now legal to sell in interstate commerce. The result has been that storefronts and online retailers have flooded the market with these products, many with unsubstantiated therapeutic claims.[69]

As such, the FDA has commented its "biggest concern" with respect to the sale of CBD items "is the marketing of CBD products that make unsubstantiated therapeutic claims to prevent, diagnose, mitigate, treat, or cure serious diseases, but have not obtained new drug approvals."[70]

Indeed, the agency also noted these concerns in its press release announcing its approval of Epidiolex. The FDA stated in that release that it would "continue to support rigorous scientific research on the potential medical uses of marijuana-derived products and work with product developers who are interested in bringing patients safe and effective, high quality products."[71] The agency stressed, however, that it was "prepared to take action when... [it] see[s] the illegal marketing of CBD-containing products with serious, unproven medical claims."[72] It took this stance because "[m]arketing unapproved products, with uncertain dosages and formulations can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases."[73]

In March 2019, the then-Commissioner of the FDA, Scott Gottlieb, commented that the agency was using its discretion to focus enforcement efforts on the worst CBD product offenders first.[74] Later, the Director of the Office of Dietary Supplement Programs stated instead that enforcement discretion was not being used with respect to CBD products, but that the greatest concern of the agency was those products claiming to treat, diagnose, or cure serious diseases.[75]

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69. Testimony of Amy Abernethy, *supra* note 32.

70. Testimony of Amy Abernethy, *supra* note 32.

71. U.S. Food & Drug Admin., *supra* note 11.

72. *Id.*

73. U.S. Food & Drug Admin., *supra* note 11.

74. *FDA Chairman Explains CBD Regulatory Pathway,* YOUTUBE (Mar. 21, 2019), https://www.youtube.com/watch?v=b1vf4PxK1rs [https://perma.cc/JB83-ZJU7].

75. Elizabeth Oestreich, *CBD Enforcement – Who is Keeping Watch?*, FOOD & DRUG L. INST., https://www.fdli.org/2020/01/cbd-enforcement-who-is-keeping-watch/ [https://perma.cc/2BUR-5YEV]; Stephen Daniells, *FDA: We Do not Have a Policy of Enforcement Discretion for CBD Products*, NUTRAINGREDIENTS-USA.COM (Aug. 1, 2019), https://www.nutraingredients-usa.com/Article/2019/05/17/FDA-We-do-not-have-a-policy-of-enforcement-discretion-for-CBD-products [https://perma.cc/R24M-25UU].

The FDA has taken action against such violative CBD products by sending warning letters to a number of companies.[76] The FDA sent 21 warning letters in 2020; 22 warning letters in 2019; one letter in 2018; four letters in 2017; 22 letters in 2016 (to 8 companies in total); and 18 letters in 2015 (to 6 companies in total).[77] Some of the products identified in the November 2019 warning letters were noted by the FDA to be "marketed for infants and children — a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD."[78] Another one of the 2019 warning letters was sent to Curaleaf, which at the time operated in 12 states.[79] Of note, its CBD lotion and skin patches were sold by a major retailer, CVS Health.[80] One product that was the subject of a 2020 warning letter was sold as an alternative to opioids, and another as a treatment to opioid addiction.[81]

In addition to the FDA, the Federal Trade Commission (FTC) has also taken action with respect to illegal advertising claims by companies marketing CBD products. The FTC announced in September 2019 that it had sent three such letters to companies that had claimed its companies treated or cured a variety of serious diseases.[82] It had also joined three warning letters sent by the FDA earlier in 2019.[83] In December 2020, the FTC announced "the first law enforcement crackdown on deceptive claims" with respect to CBD products, called

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76. Warning letters are further described within Part III of this Article.

77. *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD & DRUG ADMIN. (Aug. 5, 2021), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products [https://perma.cc/4MF8-7LYH].

78. *FDA Warns 15 Companies for Illegally Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns.* U.S. FOOD & 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 [https://perma.cc/424C-TJPN].

79. Carla K. Johnson, *FDA Warns Top Marijuana Company for Making CBD Health Claims*, ABC NEWS (July 23, 2019, 7:12 PM), https://abcnews.go.com/Health/wireStory/fda-warns-top-marijuana-company-making-cbd-health-64519999 [https://perma.cc/AEW9-9LMQ].

80. *Id.*

81. *FDA Warns Companies Illegally Selling CBD Products to Treat Medical Conditions, Opioid Addiction*, U.S. FOOD & DRUG ADMIN. (Apr. 23, 2020), https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products-treat-medical-conditions-opioid-addiction [https://perma.cc/M86Z-L3RS].

82. *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatments for Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, FED. TRADE COMM'N (Sept. 10, 2019), https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbd-infused [https://perma.cc/R4GB-DPFE].

83. *Id.; see also FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, FED. TRADE COMM'N, (Apr. 2, 2019), https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companies-advertising [https://perma.cc/65XG-N5YN].

CBDeceit.[84] As part of that initiative, the FTC announced six settlements against "sellers of CBD-containing products for allegedly making a wide range of scientifically unsupported claims about their ability to treat serious health conditions."[85] Five of these settlements involved payments to the FTC, ranging from $20,000 to $85,000.[86]

At the same time that the FDA issued the warning letters in November 2019, it also published a revised Consumer Update regarding the safety of CBD products generally.[87] The FDA noted that "CBD has the potential to harm you," including through the risk of liver injury, drug interactions, injury resulting from use with alcohol or other drugs, and male reproductive toxicity or damage to fertility in males or male offspring of women who have been exposed.[88] The guidance also noted that CBD can cause side effects, including changes in alertness, gastrointestinal distress, and changes in mood.[89]

The FDA provided an update in March 2020 as to its work in the area of CBD product regulation.[90] The press release described the FDA's action in updating the public "on concerns about potential harm from CBD products," and its intent to "continue to expand [its] educational efforts on this front."[91] The update also highlighted the FDA's need for "reliable and high-quality data . . . about the science, safety and quality of many" CBD products.[92] To that end, the FDA re-opened a public comment portal indefinitely "to allow the public to comment and to share relevant data with the agency."[93] Finally, the FDA addressed the issue of enforcement, stating that it was "currently evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding factors the agency intends to take into account in prioritizing enforcement decisions."[94]

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84. *FTC Announces Crackdown on Deceptively Marketed CBD Products*, FED. TRADE COMM'N (Dec. 17, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-announces-crackdown-deceptively-marketed-cbd-products [https://perma.cc/5EYB-8UY4].

85. *Id.*

86. *Id.*

87. *See generally What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, U.S. FOOD & DRUG ADMIN. (Mar. 3, 2020), https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis [https://perma.cc/8RUD-3Q5S].

88. *Id.*

89. *Id.*

90. Stephen M. Hahn, *FDA Advances Work Related to Cannabidiol Products with Focus on Protecting Public Health, Providing Market Clarity*, U.S. FOOD & DRUG ADMIN (Mar. 5, 2020), https://www.fda.gov/news-events/press-announcements/fda-advances-work-related-cannabidiol-products-focus-protecting-public-health-providing-market [https://perma.cc/U8UM-FV92].

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

Specifically, "[a]ny enforcement policy would need to further the goals of protecting the public and providing more clarity to industry [sic] and the public regarding the FDA's enforcement priorities while we take potential steps to establish a clear regulatory pathway."[95]

In July 2020, the FDA submitted draft guidance concerning enforcement against CBD products to the White House Office of Management and Budget.[96] That enforcement guidance was later withdrawn in early 2021 as part of the new administration's withdrawal of pending rules.[97]

Beyond federal agency enforcement with respect to CBD items, consumers themselves have brought class actions against certain CBD products; those actions, however, are largely stayed pending the issuance of new federal regulations.[98] These cases have been brought on various grounds, including mislabeling as to the quantity of CBD contained in the product purchased, which was less than advertised,[99] and specific representations by sellers that CBD was legal to sell in the United States.[100] In some instances, those cases were stayed because the court concluded that the case should not proceed prior to the FDA issuing new regulations that it was in the process of creating.[101]

II. GLUTEN-FREE LABELING

Gluten-free labeling is another area of recent FDA action with respect to regulation and enforcement. As is the case for CBD products, consumer health and safety may be at issue with respect to the marketing and sale of such products when such products do not conform to agency standards. A key difference between gluten-free products and CBD items, however, is that within the last decade, regulatory standards for gluten-free claims have been set that provide a consistent standard for gluten-free packaged food items. Evidence shows that a gluten-free label does often accurately reflect these parameters, even absent extensive agency enforcement. Despite the significant progress

95. *Id.*

96. Laura Drotleff, *FDA submits CBD enforcement policy draft guidance to White House*, HEMP INDUSTRY DAILY (July 23, 2020), https://hempindustrydaily.com/fda-submits-cbd-enforcement-policy-draft-guidance-to-white-house/ [https://perma.cc/TL9L-A7BX].

97. *Regulatory Freeze Pending Review*, THE WHITE HOUSE (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/ [https://perma.cc/UP4C-RRFV].

98. Nathalie Bougenies, *Patchwork of Judicial Decisions Exacerbates Confusion on Legality of CBD Products*, ABOVE THE LAW (June 30, 2020), https://abovethelaw.com/2020/06/patchwork-of-judicial-decisions-exacerbates-confusion-on-legality-of-cbd-products/ [https://perma.cc/N66M-75TM].

99. *Glass v. Global Widget, LLC*, No. 2:19-cv-01906, 2020 WL 3174688, at 2 (E.D. Cal. June 15, 2020).

100. *Id.*

101. *See, e.g., Snyder v. Green Roads of Fla. LLC*, 430 F.Supp. 3d 1297, 1309 (S.D. Fla. Jan. 3, 2020).

in this area, however, the regulatory standard for gluten-free packaged food items presents certain challenges for companies seeking to make gluten-free claims in accordance with agency rules. These challenges arise as companies seek to both understand the nuances of the applicable rule and to ensure that their manufacturing processes do not result in gluten being inadvertently introduced into their packaged food products in quantities in excess of the permitted threshold. As a result, there is still room for increased agency enforcement against non-compliant products labeled as gluten-free, in order to protect consumer health.

A. Background

Developments in the regulation of gluten-free labeling have been prompted, in part, by greater recognition of the prevalence of celiac disease and non-celiac gluten sensitivity in the United States, and the need for patients with those conditions to reliably access genuinely gluten-free products. Celiac disease is an autoimmune disorder which is "precipitated, in genetically predisposed persons, by the ingestion of gluten, the major storage protein of wheat and similar grains."[102] Celiac has been estimated to affect around 1% of the population in many world regions.[103] Celiac diagnosis was aided in the 1980s with the identification of certain antibodies circulating in the plasma of untreated patients; "[t]his was a major step forward as prior to this development, [celiac disease] could be diagnosed only on the basis of clinical suspicion and intestinal biopsy."[104] New serologic tests have since been identified "as a first step in patients with symptoms suggestive of" celiac disease.[105] A celiac diagnosis is then generally confirmed with a small intestinal biopsy.[106]

Currently, celiac disease can only effectively be treated through a gluten-free diet. [107] The diet requires avoiding the ingestion of even small amounts of gluten-containing grains.[108] Treatment by adherence to the gluten-free diet can result in "normalization of standardized mortality rate, as well as improvement in the majority of related

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102. Peter H.R. Green and Christophe Cellier, *Celiac Disease*, N. ENGL. J. MED. 357;1731 (2007).

103. Dharmesh Kaswala et al., *Celiac Disease: Diagnostic Standards and Dilemmas*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (June 16, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5548238/ [https://perma.cc/WH3U-HF7D].

104. *Id.*

105. *Id.*

106. *Id.*

107. Daniel A. Leffler et al., *Factors that Influence Adherence to a Gluten-Free Diet in Adults with Celiac Disease*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (June 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756800/ [https://perma.cc/G3MQ-KZFZ].

108. *Id.*

problems including osteoporosis and osteopenia, anemia, risk of malignancy, gastrointestinal symptoms, and in several studies, psychological well-being and quality of life."[109] The Food Allergen Labeling and Consumer Protection Act of 2004, which directed that a definition of the term "gluten-free" be adopted, referenced the occurrence of celiac disease within its findings, including the fact that that "the current recommended treatment is avoidance of glutens in foods that are associated with celiac disease."[110] The occurrence of celiac disease is therefore the major impetus for the need for consistent and accurate gluten-free labeling.

In addition to celiac patients, individuals with non-celiac gluten sensitivity (NCGS) also benefit from a gluten-free diet. "NCGS is a condition characterized by intestinal and extra-intestinal symptoms related to the ingestion of gluten-containing foods in patients in whom celiac disease and wheat allergy have been excluded."[111] "In general, symptoms in patients with NCGS appear with the ingestion of gluten and disappear or ameliorate with gluten avoidance."[112]

The gluten-free diet has also been recently adopted as a fad by individuals without a proven medical need for it.[113] "Nowadays, a gluten-free diet is fashionable and is promoted by many celebrities... Lack of gluten in food consumed by people who tolerate it well may not bring favorable results."[114] "A 2013 study found that 65% of American adults think gluten-free foods are healthier, and 27% choose gluten-free

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109. *Id.*

110. Pub. L. No. 108-282 (Aug. 2, 2004) (Other findings related to celiac disease were that "celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs" and that "a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States in 0.5 to 1 percent of the general population.").

111. Maria Raffaella Barbaro et al., *Recent advances in understanding non-celiac gluten sensitivity*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (Oct. 11, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6182669/ [https://perma.cc/U68R-D7LF].

112. *Id.*

113. Steve W. Martinez, *Introduction of New Food Products With Voluntary Health- and Nutrition-Related Claims, 1989-2010*, U.S. DEP'T OF AGRICULTURE (Feb. 2013) ("The largest increase in health- and nutrition-related claims over 2001 to 2010 was for 'no *gluten*'"; "[w]hile claims related to gluten . . . were used sparingly, if at all, prior to 2001, they ranked among the leading claims by 2010"). Moreover, based on an online poll of 1,881 U.S. consumers, only about 10 percent of gluten-free consumers purchased the products because someone in their household had celiac disease or intolerance to gluten. The top reason given for purchasing gluten-free products is the perception that they are generally healthier (46 percent), followed by weight management (30 percent), and generally higher in quality (22 percent) (citing Packaged Facts, *Gluten-Free Foods and Beverages in the U.S.*, 3rd ed. (Feb. 2011), and C. Scott-Thomas, *Celiac Disease May Have Little Influence on Soaring Gluten-Free Market*, Food Navigator-USA.com (Feb. 4, 2011)).

114. Anna Roszkowska et al., *Non-Celiac Gluten Sensitivity: A Review*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (May 28, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6630947/ [https://perma.cc/T37M-E798].

products to aid in weight loss."[115] In 2015, a Gallup poll found that one in five Americans surveyed reported that they tried to include gluten-free foods in their diets, a percentage far in excess of the 0.5% of individuals estimated to have celiac disease in North America.[116] The gluten-free diet, however, "may increase the risks for nutritional deficiencies," and is often significantly more expensive than a typical diet; further, as of 2017, there were "no published studies on the benefits of the gluten-free diet on the weight status of those without celiac disease."[117] A perception of the gluten-free diet as a diet fad complicates the issues of gluten-free labeling, and may color views of the need for robust agency enforcement.

Marketing of gluten-free products has grown rapidly in recent years. "Between 2004 and 2011, the market for gluten-free products grew at an annual rate of 28%, with an estimated $2.6 billion in sales in 2012."[118] "The gluten-free products market size was valued at $4.3 billion in 2019, and is estimated to reach $7.5 billion by 2027."[119]

B. Regulatory Standards for Gluten-Free Claims

Before 2013, there was no defined federal regulatory standard for "'gluten-free' claims" made in product labeling separate from "free from" claims.[120] "The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) directed the [U.S.] Department of Health and Human Services (HHS) to define and permit the use of the term 'gluten-free' in the labeling of FDA-regulated foods."[121] In August 2013, the FDA issued a final rule "to define the term 'gluten-free' for voluntary use in the labeling of foods[;]" the rule became effective August 2014.[122]

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115. Amy L. Jones, *The Gluten-Free Diet: Fad or Necessity?*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (May 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5439366/ [https://perma.cc/ZM4E-GK6V].

116. Rebecca Riffkin, *One in Five Americans Include Gluten-Free Foods in Diet*, GALLUP (July 23, 2015), https://news.gallup.com/poll/184307/one-five-americans-include-gluten-free-foods-diet.aspx [https://perma.cc/H2ZT-ZGVD]; *Global Prevalence of Celiac Disease*, CELIAC DISEASE FOUNDATION (Aug. 23, 2018), https://celiac.org/about-the-foundation/featured-news/2018/08/global-prevalence-of-celiac-disease/ [https://perma.cc/L5ME-4WYG]. Of course, one would expect that all or nearly all Americans do include gluten-free foods in their diets, as many fruits and vegetables are generally naturally gluten-free.

117. Jones, *supra* note 119.

118. *Id.*

119. Raju Kale et al., *Gluten-free Products Market Size & Growth: Industry Overview by 2027*, ALLIED MARKET RESEARCH (Apr. 2020), https://www.alliedmarketresearch.com/gluten-free-products-market [https://perma.cc/DL5A-TWQ4].

120. Gluten and Food Labeling, *supra* note 1 ("Before the regulation was issued in 2013, there were no U.S. standards or definitions for the food industry to use in labeling products as 'gluten-free.'"); 21 C.F.R. § 101.13 (2016).

121. *Questions and Answers on the Gluten-Free Food Labeling Final Rule*, U.S. FOOD & DRUG ADMIN (Aug. 13, 2020), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-gluten-free-food-labeling-final-rule) [https://perma.cc/M2JH-WUSC].

122. 21 C.F.R. § 101 (2013).

Foods may be labeled as "gluten-free," "no gluten," "free of gluten," or "without gluten" if they contain any unavoidable presence of gluten below 20 parts per million of gluten.[123] In addition, the food item must either inherently not contain gluten or must not contain any of the following: "[a]n ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains[;]" "[a]n ingredient derived from these grains that has *not* been processed to remove gluten[;]" or "[a]n ingredient derived from these grains that *has* been processed to remove gluten, but results in the food containing more than 20 ppm of gluten."[124] The gluten-free labeling rule applies to "all foods and beverages (including packaged foods, dietary supplements, fruits and vegetables, shell eggs, and fish)," with the exception of "[m]eat, poultry, and certain egg products" subject to USDA jurisdiction, as well as "[m]ost alcoholic beverages[,]" which are subject to the jurisdiction of the U.S. Department of the Treasury.[125] Gluten-free labeling is voluntary and foods meeting the definition of gluten-free need not be labeled with the term "gluten-free."[126] Per the FDA, in addition to benefiting celiac consumers, the gluten-free labeling rule "also benefits the food industry by establishing a level playing field among manufacturers of products labeled 'gluten-free.'"[127]

In August 2020, the FDA also issued a final rule regarding compliance requirements for gluten-free-labeled foods that are fermented or hydrolyzed or contain fermented or hydrolyzed ingredients.[128] Such fermented foods include, for example, "yogurt, sauerkraut, pickles, cheese, green olives, FDA-regulated beers and wines," and items with hydrolyzed ingredients include "soups, sauces, and seasonings."[129]

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123. *Gluten-Free Diet & Food Label Reading Guide*, CELIAC DISEASE FOUND., https://celiac.org/main/wp-content/uploads/2017/07/Combined-Gluten-Free-Diet-and-Food-Label-Reading-Guide.pdf [https://perma.cc/62GE-STEQ].

124. Gluten and Food Labeling *supra* note 1; 21 C.F.R. § 101.91 (2020). Gluten-free labeling regulations are separate from requirements that a label indicate the possible presence of certain allergens, including wheat. *See Gluten-Free Diet & Food Label Reading Guide*, CELIAC DISEASE FOUND., https://celiac.org/main/wp-content/uploads/2017/07/Combined-Gluten-Free-Diet-and-Food-Label-Reading-Guide.pdf [https://perma.cc/7QCK-BG35] ("[i]f a product is labeled 'gluten-free' and states that it is made in the same facility as products containing wheat, it is still safe for people with celiac disease to consume. The gluten-free label represents that the procedures put in place to prevent cross-contact with gluten meet FDA standards"). However, naturally gluten-free products, especially grains, not labeled as gluten-free that contain a "'may contain' . . . wheat" statement or similar wording might contain more than 20 ppm of gluten. *Id.*

125. Gluten and Food Labeling, *supra* note 1.

126. Questions and Answers on the Gluten-Free Food Labeling Final Rule, *supra* note 125

127. *Id.*

128. *FDA Issues Final Rule on Gluten-Free Labeling of Fermented and Hydrolyzed Foods*, U.S. FOOD & DRUG ADMIN. (Aug. 12, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-final-rule-gluten-free-labeling-fermented-and-hydrolyzed-foods [https://perma.cc/T7HP-DHTK].

129. *Id.*

Such foods present a unique challenge to enforcement because there is "no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented or hydrolyzed foods in terms of equivalent amounts of intact gluten proteins."[130] The final rule stated that it would therefore evaluate compliance of such foods "based on records that are made and kept by the manufacturer of the food . . . and made available to use for inspection and copying."[131] The records need to provide adequate assurance that the food or ingredients used in the food are 'gluten-free' before fermentation or hydrolysis."[132]

Separate from the regulations of the FDA, the U.S. Department of Agriculture (USDA) regulates the gluten-free labeling of certain types of foods. These include "[m]eat products, such as hot dogs[,]" "[p]oultry products, such as canned chicken[,]" "[e]gg products, such as certain liquid egg products[,]" and "[m]ixed food products containing more than 3% raw meat or 2% or more cooked meat or poultry."[133] Unlike the FDA, the USDA requires that gluten-free claims be submitted to it in advance for approval.[134]

Third party gluten-free certifications are also available for products labeled as gluten-free. These include the National Foundation for Celiac Awareness's Gluten-Free Certification; the National Celiac Association Recognition Seal (formerly from the Celiac Support Association), which requires products to test at 5 ppm of gluten or less; the Gluten Intolerance Group's Gluten-Free Certification Organization (GFCO); and the NSF's Gluten-Free Certification.[135] Gluten-free certification "assures consumers that there is third-party oversight confirming the legitimacy of the manufacturer's gluten-free processes and claims."[136]

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130. *Id.*

131. *Id.*

132. *Id.*

133. Tricia Thompson, *USDA-regulated foods and gluten-free labeling*, GLUTEN FREE WATCHDOG (May 20, 2017), https://www.glutenfreewatchdog.org/news/usda-regulated-foods-and-gluten-free-labeling/ [https://perma.cc/GV2J-RXZ5].

134. *FSIS Compliance Guidance for Label Approval*, USDA-FSIS (July 2020), https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES.

135. *Going Gluten-Free: Third-Party Gluten-Free Certification*, NUTRITIONAL OUTLOOK (May 20, 2015), https://www.nutritionaloutlook.com/articles/going-gluten-free-third-party-gluten-free-certification [https://perma.cc/F2CA-Z9NW]; *GF Certification Seal Program*, NAT'L CELIAC ASS'N (Aug. 11, 2018), https://nationalceliac.org/blog/gf-certification-seal-program/ [https://perma.cc/D255-A2DJ]; *Certified Gluten-Free Products*, NAT'L CELIAC ASS'N, https://nationalceliac.org/resources/gluten-free-recognition-seal-program/ [https://perma.cc/RE9S-3ZP2]; *GFCO Certification*, GLUTEN INTOLERANCE GROUP, https://gfco.org/certification/ [https://perma.cc/3G7A-UYCV].

136. *Gluten-Free Certification*, BEYOND CELIAC, https://www.beyondceliac.org/gluten-free-diet/gluten-free-certification/ [https://perma.cc/R3F6-V8ZU].

C. Post-Implementation Enforcement

Subsequent to the implementation of the gluten-free labeling rule, there has been debate over the extent of industry compliance with the rule and the need for any increased enforcement of the rule by the FDA. Some evidence points to a large degree of compliance with the gluten-free labeling standard. The FDA has advised the public that they can report non-compliance with the rule; specifically, consumers can report issues with gluten-free labeling to the FDA either via MedWatch (the FDA's Safety Information and Adverse Event Reporting Program) or via the consumer complaint coordinator in their area.[137] The FDA has in some instances issued warning letters in the past based on alleged violations of the gluten-free labeling standard.[138]

Some evidence indicates that a large percentage of packaged food products labeled as gluten-free does comply with the gluten-free labeling rules, and that the rule functions effectively with the current level of agency enforcement to protect consumer health and safety. For example, in 2017, the FDA assessed 702 samples from more than 250 products labeled as gluten-free, and found that only one product did not comply with the provisions of the gluten-free labeling regulation.[139] A researcher with the Celiac Disease Center at Columbia University, along with Tricia Thompson of Gluten Free Watchdog (referenced later within this section) evaluated gluten-free-labeled foods purchased between April 2011 and April 2014 (i.e., before the date where manufacturers were expected to comply with the FDA gluten-free labeling standard but after the 2013 announcement of the relevant standard) from retail establishments in the United States.[140] They found that "approximately 95% of labeled gluten-free food products tested < 20 p.p.m. gluten, with approximately 87% testing < 5 p.p.m. gluten."[141] The study noted that "[c]onsumers with gluten-related disorders should be able to trust the gluten-free label[,]" and that they hoped that the percentages of truly gluten-free products would increase after the compliance date of the FDA standard.[142] It has been argued that

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137. *Gluten and Food Labeling, supra* note 1.

138. *See, e.g., Warning Letters to Popsaolot, LLC* , U.S. FOOD & DRUG ADMIN. (June 21, 2016), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/popsalot-llc-493726-04302020 [https://perma.cc/7ZRJ-R3U9]; and *Warning Letter to Summit Beverage Group, LLC,* U.S. FOOD & DRUG ADMIN. (Oct 17, 2014).

139. *FDA Sampling Finds High Level of Compliance with Gluten-Free Standards*, U.S. FOOD & DRUG ADMIN. (May 30, 2017), https://www.fda.gov/food/cfsan-constituent-updates/fda-sampling-finds-high-level-compliance-gluten-free-standards [https://perma.cc/R5MU-33BJ].

140. T. Thompson and S. Simpson, *A comparison of gluten levels in labeled gluten-free and certified gluten-free foods sold in the United States*, EUR. J. CLIN. NUTR. (2014), https://celiacdiseasecenter.columbia.edu/wp-content/uploads/2018/12/2-2014-A-comparison-of-gluten-levels-in-labeled-gluten-free-and-certified-gluten-free-foods-sold-in-the-United-States.pdf [https://perma.cc/ZLX5-R275].

141. *Id.*

142. *Id.* at 2.

despite certain issues with gluten-free labeling (discussed further within this section), gluten-free consumers "should rest assured that most of the labeled GF foods that they purchase are safe."[143] One study submitted for publication in 2014 examined 275 gluten-free labeled foods and found gluten-free labeling compliance of approximately 98.9%.[144]

Some other studies, especially around and before the time the gluten-free labeling standard became effective, observed more varying levels of gluten in products labeled as gluten-free. One study, using samples from products collected in May 2013, tested seventy-eight samples and found that sixteen of them (20.5%) contained gluten levels over the 20 ppm threshold.[145] Other studies conducted in the early 2000's also indicated the presence of inaccurate gluten-free labels in the marketplace.[146] It is possible, though not entirely clear, that the gluten-free labeling standard itself caused a change in the use of the gluten-free label to indicate only foods at 20 ppm gluten or below; but certainly, the regulatory standard did define and make clear to consumers what "gluten-free" was intended to mean.

Some concerns about industry compliance with the gluten-free labeling standard remain. One source raising such concerns is Tricia Thompson, a registered dietician who runs the blog Gluten Free Watchdog.[147] In 2018, she and Kaki Schmidt (an individual consumer and member of Gluten Free Watchdog) filed a Citizen Petition requesting "that the Commissioner of the FDA establish a specific protocol for increased surveillance, investigation and enforcement of potential Facial Misbranding violations" of the gluten-free labeling regulations.[148] They defined the term "Facial Misbranding" as "when a product label displays a 'gluten-free' claim but the ingredients list includes an ingredient that is prohibited under FDA rules from being contained in any product labeled 'gluten-free' (e.g., barley malt, barley malt extract,

143. Amy Keller, *Timely Topics in Gluten-Free Labeling*, Practical Gastroenterology (Dec. 2019), https://med.virginia.edu/ginutrition/wp-content/uploads/sites/199/2019/12/Parrish-December-Gluten-Free-Labeling-2019.pdf.

144. Girdhari M. Sharma et al., *Gluten detection of foods available in the United States – A market survey*, FOOD CHEMISTRY 169 (2015).

145. Hyun Jung Lee, Zach Anderson, and Dojin Ryu, *Contamination in Foods Labeled as "Gluten Free" in the United States*, 77 J. OF FOOD PROT. No. 10 (2014).

146. Michelle R. Worosz and Norbert L.W. Wilson, *A Cautionary Tale of Purity, Labeling and Product Literacy in the Gluten-Free Market*, 46 The J. OF CONSUMER AFF. No. 2, 288, 301 (2012) (citing Ashley L. Lardizabal, LynnM. Niemann, and Sue L. Helfe, *Immunochemical Analysis of Various Foods and Food Ingredients for Detectable Gluten Content: Implications for Wheat-Allergic and Celiac Sprue Patients*, 109 Journal of Allergy and Clinical Immunology (2002) "[a] study of unidentified wheat in food found that 20% of products labeled wheat-free or gluten-free contained twenty-two to seventy-one parts per million . . . of gluten.").

147. Thompson, *supra* note 137.

148. FDA Citizen Petition, Aug. 18, 2017.

barley malt syrup, wheat [except in limited circumstances with clear additional markings and language])."[149] The petition called for the FDA to take action in response to the issue, namely, by "establish[ing] a reporting system on its website for consumers/consumer groups to electronically report Facial Misbranding to [the] FDA[,]" and routinely issuing Warning Letters within thirty days of receiving electronically submitted reports of facial misbranding.[150] The petition proposed that in the alternative, the FDA implement a "Facial Misbranding Initiative . . . utilizing consumer submissions and information collected through other methods of surveillance."[151]

Ms. Thompson also authored a 2018 post on her Gluten Free Watchdog blog examining the number of FDA recalls relating to gluten-free products, noting that a search of the FDA's recall database showed only two recalls since January 2016 where the reason for the recall cited by the FDA was the presence of gluten.[152] A similar search as of August 2020 shows three additional recalls for the presence of gluten.[153] Ms. Thompson noted in her blog post that her blog had reported many more products to the FDA as being facially misbranded under the gluten-free labeling rule (14 products in 2016, 17 products in 2017, and 9 products as of the date of her blog post in 2018).[154] These reported products were facially misbranded only; these reports did not include foods tested by her blog to contain gluten quantities in excess of the 20 ppm standard.[155] Ms. Thompson has also notified companies and the FDA of other issues with foods that contain ingredients with gluten or are otherwise misbranded.[156]

Other anecdotal evidence indicates that there is still room for improvement in the enforcement of gluten-free claims to the 20 ppm standard. For example, some celiac patients report issues with Cheerios.[157] Cheerios are made from oats; oats are naturally gluten-free but

149. *Id.*

150. *Id.*

151. *Id.* at 3.

152. Tricia Thompson, *Is the FDA enforcing the gluten-free labeling rule?*, GLUTEN FREE WATCHDOG (June 5, 2018), https://www.glutenfreewatchdog.org/news/is-the-fda-enforcing-the-gluten-free-labeling-rule/ [https://perma.cc/H966-97AR].

153. *Recalls, Market Withdrawals, & Safety Alerts* (July 16, 2021), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts [https://perma.cc/C5X9-F9B4] (Sierra Soups Pasta e Fagioli: Feb. 24, 2020: product contains undeclared gluten; Martha White Cornbread and Muffin Mix, Sept. 9, 2019: possible presence of gluten; and EnviroKidz Choco Chimps, Gorilla Munch and Jungle Munch cereals, May 9, 2019: undeclared gluten).

154. Thompson, *supra* note 156.

155. *Id.*

156. Jill Neimark, *Gluten-Free Food Labels Aren't As Accurate As You May Think*, THE HUFFINGTON POST (Sept. 12, 2018), https://www.huffpost.com/entry/gluten-free-labels-misleading_n_5b96773ae4b0cf7b0041f9a8 [https://perma.cc/H9PC-8333].

157. Melinda Dennis and Tricia Thompson, *NCA Stance on Gluten Free Oats*, NAT'L CELIAC ASS'N (Feb. 2018), https://nationalceliac.org/nca-stance-on-gluten-free-oats/.

may become contaminated with gluten in processing.[158] Cheerios are marketed and labeled as gluten-free.[159] In February 2018, the National Celiac Association opined that it was "not comfortable recommending General Mills Cheerios or Lucky Charms (both mechanically sorted) at this time."[160] Yet the association felt "comfortable with the use of Quaker GF oats (mechanically sorted) at this time given their transparent and very strong testing protocol."[161] The Canadian Celiac Association "recommends that people with celiac disease or gluten sensitivity DO NOT consume" gluten-free labeled Cheerios due to the mechanical sorting system used by General Mills.[162] "Oats are an extremely high risk grain and even 'gluten-free oats' are at high risk for gluten contamination[;]" further, "[i]t is very difficult to remove gluten-containing grains from oats using optical and mechanical technology alone because barley and wheat are similar in size, shape and color as oats."[163] According to the Canadian Celiac Association, "[g]luten contamination in oats is not distributed evenly through a batch; therefore, 'hot spots' of high contamination can occur."[164] The scientific advisors to the Canadian association were "not convinced that the testing procedures described by General Mills" were sufficient to detect those hot spots of contamination.[165] Anecdotally, some consumers with celiac disease have reported reactions to gluten-free-labeled Cheerios.[166]

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158. *Id.* ("Until recently, GF oats have been grown and processed under a purity protocol (dedicated GF oats, field, truck, facility and processing) and tested using best current practices. Beginning in 2013, certain GF grain millers started selling mechanically/optically sorted . . . GF oats and oat-based products . . . The testing process to determine possible cross contamination is the key to choosing GF oats, regardless of the type of protocol used.").

159. *Oats for All: See how we made Cheerios gluten free*, CHEERIOS, https://www.cheerios.com/our-gluten-free-process/ [https://perma.cc/YY6N-7MFY] ("[t]he Cheerios you've always loved. Now gluten-free").

160. Melinda Dennis and Tricia Thompson, *NCA Stance on Gluten Free Oats*, NAT'L CELIAC ASS'N (Feb. 2018), https://nationalceliac.org/nca-stance-on-gluten-free-oats/ [https://perma.cc/9BB2-YNSW].

161. *Id.*

162. *Notice about GF Cheerios*, CANADIAN CELIAC ASS'N, https://www.celiac.ca/439-2/ [https://perma.cc/R95X-KQ4P].

163. *Id.*

164. *Id.*

165. *Id.*

166. Vanessa Wong, *"Not Safe for Celiacs" – Gluten-Free Cheerios Are Still Drawing Complaints*, BUZZFEED NEWS (July 6, 2017), https://www.buzzfeednews.com/article/venessawong/people-with-celiac-still-complaining-about-cheerios [https://perma.cc/ESA2-K35L]. Separate from the issue of the appropriate sorting mechanism for oats used in gluten-free products, in 2015 General Mills issued a voluntary recall for Cheerios produced in its Lodi, California facility. The 2015 contamination of gluten-free-labeled Cheerios occurred to the inadvertent introduction of wheat flour into certain batches of Cheerios at that processing facility. *Haddix v. Gen. Mills, Inc.*, 2016 U.S. Dist. LEXIS 65108, No. 2:15-cv-02625-MCE-AC (E.D. Cal. May 17, 2016). Specifically, the contamination leading to the recall occurred because "General Mills unloaded its gluten-free flour onto trucks that had previously carried wheat flour because of a rail car incident." *Hamilton v. Gen. Mills, Inc.*, 2016 U.S.

Thus, evidence indicates that many industry actors certainly do comply with the 20 ppm gluten threshold applicable to gluten-free labeled food items. However, there is also some indication that certain issues remain with respect to industry compliance with aspects of the gluten-free labeling rule, including complying with the 20 ppm threshold for products containing oats, and ensuring that prohibited ingredients are not used in products containing a gluten-free label.

D. Other Areas for Action in Gluten-Free Labeling

Beyond the issue of gluten-free labeling of packaged food items, there certainly remains room for action with respect to promoting consumer health and welfare in connection with other types of items that are or could be labeled as gluten-free. Such action items could be addressed by way of legislative action or local regulation and enforcement, instead of regulation and enforcement by the FDA. For example, the Gluten in Medicine Disclosure Act was introduced in Congress and proposed to require drug manufacturers to label medications for human use with a disclosure as to whether gluten was contained in these products.[167] The FDA has taken action to support this particular health concern; namely, in 2017, the FDA released draft guidance for industry concerning recommendations for the labeling of gluten in drug products.[168]

Further, as discussed earlier in this Article, the gluten-free labeling requirements apply to several types of items, including "packaged foods," but not to gluten-free claims made elsewhere, such as prepared foods served in restaurants.[169] The FDA recommends that "[g]iven the public health significance of gluten-free labeling, restaurants making a gluten-free claim on their menus should be consistent with the FDA's

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Dist. LEXIS 97812, Civ. No. 6:16-cv-382-MC (D. Or. Jul. 27, 2016). The current debate over the safety of Cheerios for the gluten-free consumer is based on separate processing concerns than those present with respect to the earlier voluntary recall. *See also Hamilton v. Gen. Mills, Inc.*, 2016 U.S. Dist. LEXIS 1542425, Civ. No. 6:16-cv-382-MC (D. Ore. Nov. 2, 2016) (dismissing defendant's complaint based on the "isolated occurrence where, due to a transportation breakdown, gluten-free oat flour was contaminated with traces of wheat flour, and then used to make Cheerios mislabeled as gluten-free" and denying defendant's motion to amend complaint to include comments from Gluten Free Watchdog concerning the production and testing of Cheerios for gluten, which, the court stated, "while interesting, allows the court to do no more than engage in speculative gossip[,]" and "has no nexus to the specific conduct alleged in the complaint before the court"; the court also noted that it was "not an administrative agency charged with the policing of the general production practices of the cereal industry").

167. H.R. 2074 & S. 3021, 116th Congress (2019-2020).

168. *Gluten in Drug Products and Associated Labeling Recommendations; Draft Guidance for Industry; Availability*, 82 Fed. Reg. 58,618 (Dec. 13, 2017).

169. *"Gluten-Free" Means What It Says, FDA Consumer Updates,* U.S. FOOD AND DRUG ADMIN. *(May 11, 2018),* https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says [https://perma.cc/Y5TW-R8G3].

definition" of gluten-free claims made for packaged products.[170] The FDA notes that "[s]tate and local governments play an important role in oversight of restaurants[,]" and that the agency works with those governments with respect to restaurant gluten-free labeling.[171]

In addition, there are certain products on the marketplace that claim to ease the digestion of gluten.[172] As is the case for many CBD products, these items may be marketed using unproven health claims, or using ambiguous language that disclaims a product's ability to treat celiac disease but nevertheless claims to improve health through more effective gluten digestion.[173] Certainly, an agency review of such products would be warranted to ensure that consumer health is not jeopardized by products carrying possibly unproven health claims.

With respect to all these topics, further administrative or legislative action could help improve consumer health and safety for consumers with celiac disease or NCGS.

III. COMPARING REGULATORY RESPONSE AND ENFORCEMENT FOR CBD PRODUCTS AND FOR GLUTEN-FREE CLAIMS

A. Mechanisms of FDA Enforcement

CBD and gluten-free items are both subject to many of the same enforcement mechanisms available to the FDA. Where violations of regulatory significance have occurred, the FDA's practice is to send warning letters, in order to provide parties "an opportunity to take voluntary and prompt corrective action" before the agency undertakes an enforcement action.[174] Warning letters are "informal and advisory."[175] They communicate the agency's position on a matter, but do not represent an agency commitment to initiate an enforcement action. A warning letter "is issued by the FDA as a notification to a

170. *Id.*

171. Gluten and Food Labeling, *supra* note 1.

172. *Assessing the Claims of Dietary Supplements*, CELIAC DISEASE FOUND. (July 27, 2017), https://celiac.org/about-the-foundation/featured-news/2017/07/assessing-claims-dietary-supplements/ [https://perma.cc/7JN5-SA3J].

173. *See CVS Health Glutenaid Fast Acting Capsules*, CVS, https://www.cvs.com/shop/cvs-health-glutenaid-fast-acting-capsules-prodid-878021 [https://perma.cc/LDW3-F3AC] ("[p]lant-based enzyme supplement. Assists in digestion of: gluten; wheat; other grains. CVS Health Glutenaid is specially formulated for individuals who feel unwell after eating wheat or grain and thus may have an intolerance to gluten. ... This product is not intended to replace a gluten-free diet for those with Celiac Disease").

174. Regulatory Procedures Manual, § 4-1-1, https://www.fda.gov/media/71878/download#:~:text=Warning%20Letters%20are%20issued%20to,and%20to%20establish%20prior%20notice.&text=A%20Warning%20Letter%20is%20the,Cosmetic%20Act%20(the%20Act) [https://perma.cc/GP7V-HBSV].

175. *Id.* at 4.

manufacturer that it has significantly violated FDA regulations."[176] It "identifies the violation, makes clear that the company must correct the violation, and provides directions and a timeframe for the violator to inform the FDA of its plans for correction, which the FDA subsequently checks for adequacy."[177]

The FDA Regulatory Manual instructs an FDA official that when deciding whether to issue a warning letter, they should consider the following:

a. Evidence shows that a firm, product, and/or individual is in violation of the law or regulations and that failure to achieve adequate and prompt correction may result in agency consideration of an enforcement action;

b. The violation(s) are determined to be of regulatory significance, and the issuance of a Warning Letter is appropriate and consistent with agency policy, as described in Compliance Policy Guides or elsewhere; and

c. There is a reasonable expectation that the responsible firm and persons will take prompt corrective action.[178]

As described earlier within this Article, the FDA has noted that CBD products sold with unproven health claims are considered by the agency to violate several provisions of the FD&C Act. Likewise, products bearing gluten-free claims not in accordance with the regulatory labeling standard are considered by the FDA to be misbranded within the meaning of the FD&C Act.[179] Enforcement mechanisms provided within the FD&C Act include allowing the FDA to "inspect food producer facilities," to "conduct examinations and investigations," to "disseminate information about regulated products" in certain circumstances, and to "publicize information on all formal enforcement actions resolved in court."[180] Beyond these measures and issuing warning and information letters, the FDA "must coordinate with the Department of Justice . . . to enforce the [FD&C] Act through product seizures, injunctions, civil penalty proceedings, or criminal prosecutions."[181] The FD&C Act does not provide a private right of action

176. *U.S. v. Hakim*, 462 F. Supp. 3d 418 (S.D.N.Y. May 26, 2020) (citing Food and Drug Administration, *About Warning and Close-Out Letters* (Apr. 29, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters [https://perma.cc/87B3-LH2Y].

177. *Id.*

178. *Regulatory Procedures Manual*, U.S. FOOD & DRUG ADMIN. 1, 6 (June 2021), https://www.fda.gov/media/71878/download [https://perma.cc/XU9L-BU9E].

179. *See, Warning Letter to Popsalot, LLC*, U.S. FOOD & DRUG ADMIN. (June 21, 2016).

180. Kathryn B. Armstrong and Jennifer A. Staman, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*, Congressional Research Service, 1, 4 (Feb. 9, 2018).

181. *See id.*, citing to Linda Horton, *Int'l Harmonization and Mutual Recognition Agreements*, 29 Seton Hall L. Rev. 692, 698 (1998). A few recent examples of cases in which the

under which members of the public may sue to enforce its provisions.[182] The FDA has discretion with respect to the general enforcement provision of the FD&C Act.[183]

The FDA provides some statistics regarding the enforcement measures it undertakes. For fiscal year 2017— the most recent year for which data is available on the FDA website— the agency completed three seizures, issued twelve injunctions, issued 15,318 warning letters, and instituted 2,945 recall events concerning 9,199 recalled products.[184] There were no food importation debarments in 2017.[185] Of those numbers, two seizures, five injunctions, 199 warning letters, and 794 recall events involving 3,609 products were issued by the FDA's Center for Food Safety and Applied Nutrition (CFSAN).[186]

The FDA has a history of issuing warning letters with respect to both CBD products and gluten-free items. The number of warning letters related to CBD products outweighs the number of warning letters issued with respect to gluten-free items.[187] However, the evidence discussed in earlier Parts suggests that industry compliance with agency standards is more widespread in the gluten-free product marketplace than it is with respect to CBD items. Further analysis would therefore be required to determine the relative levels of enforcement by way of warning letter for violative products in each marketplace.

B. Regulatory Standards

CBD items and gluten-free products are, of course, governed by different agency standards. These standards are fundamentally different in nature and may account for some of the differences in the depth of industry understanding about the requirements of the standard and thus the level of industry compliance. Gluten-free labeling is enforced

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DOJ has brought action with respect to FDA health claims include *Hakim*, *supra* note 180; *U.S. v. Genesis II Church of Health & Healing*, Case No. 20-21601-CIV-WILLIAMS, 2020 Dist. LEXIS 10917 (S.D.Fla. May 1, 2020); and *U.S. v. Cole*, 84 F.Supp.3d 1159 (D. Or. 2015).

182. *Supra* note 186, citing 21 U.S.C. § 337(a).

183. *Id.* at 8, 9 (discussing *Heckler v. Chaney*, 470 U.S. 821, 837 (1985).

184. *FDA Enforcement Statistics Summary, Fiscal Year 2017*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/media/110196/download [https://perma.cc/N22X-D963]; *see also* FDA, *Enforcement Activity*, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/enforcement-activity [https://perma.cc/UW6E-JM89].

185. *FDA Enforcement Statistics Summary, Fiscal Year 2017*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/media/110196/download [https://perma.cc/Z3WT-WMW2].

186. *Id.*

187. *Warning Letters*, U.S. FOOD AND DRUG ADMIN. (Oct. 7, 2021), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters [https://perma.cc/93DM-PCMB]; *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD AND DRUG ADMIN. (Aug. 5, 2021), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products [https://perma.cc/AU9P-5F2L].

in one way by way of a clear numerical standard: namely, the 20 ppm threshold set forth in the regulations that were announced in 2013 and became effective in 2014.[188] That clear numerical standard does indeed have the potential to cause some confusion in the context of facial misbranding, where product manufacturers may focus only on the numerical 20 ppm cutoff and fail to take into account the fact that certain types of ingredients may not be used at all in products labeled as gluten-free. Moreover, although the 20 ppm threshold is a widely accepted level is widely accepted as a reasonable standard that will effectively protect consumer health and safety,[189] there is some debate on whether this threshold is the appropriate numerical cutoff from a medical standpoint.[190]

While a clear numerical standard also applies to the sale of CBD products—namely, that they can contain no more than 0.3% CBD—the principal enforcement issue with respect to consumer welfare is more qualitative; specifically, that CBD products are often sold in connection with unproven health claims that may confuse or mislead a consumer.[191] Sales, marketing materials, and product packaging must all be reviewed in order to confirm compliance with agency standards. Industry actors may also perceive more space for interpretation of the applicable governing standards where they are qualitative, rather than quantitative, in nature. Qualitative agency and industry evaluations of a product's health claims are necessary in order to protect consumer health and safety, and there is no practical way to convert this analysis into a quantitative assessment that can be reviewed in a more binary manner, as can be done to determine whether a gluten-free product contains more or less than the amount of gluten permitted by regulation. Identifying the additional effort and resources necessary for both the agency and for industry to devote to compliance may be useful as parties decide how to allocate resources in their enforcement or compliance efforts, depending on the particular type of actor.

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188. *"Gluten-Free" Means What It Says, FDA Consumer Updates,* U.S. FOOD & DRUG ADMIN (May 11, 2018), https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says [https://perma.cc/5VN9-DYYJ].

189. *10 Fast Facts About the FDA Gluten-Free Labeling Rule,* CELIAC DISEASE FOUND. (Aug. 5, 2014), https://celiac.org/about-the-foundation/featured-news/2014/08/fda-gluten-free-food-labeling-information-page/ [https://perma.cc/7RCW-87XA]. ("The [Celiac Disease Foundation] Medical Advisory Board supports the < 20 ppm of gluten standard for gluten-free labeling. According to Dr. Peter Green, Director of the Celiac Disease Center at Columbia University, 'The 20 ppm is a scientifically determined level of gluten that has been shown to be tolerated by those with celiac disease'").

190. Peter Makovicky et al., *Perspective: Gluten-Free Products for Some Patients with Celiac Disease Should Not Contain Trace Levels,* NCBI (May 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5421124/ [https://perma.cc/6VHK-USAW].

191. Kimberly G Wagoner, *Health Claims About Cannabidiol Products: A Retrospective Analysis of U.S. Food and Drug Administration Warning Letters from 2015 to 2019,* NAT'L LIBRARY OF MEDICINE (June 17, 2021), https://pubmed.ncbi.nlm.nih.gov/34142863/ [https://perma.cc/9C5H-3SAS].

C. Agency Enforcement

Currently, the regulation of CBD products and that of gluten-free items are similar in that there is room for more robust agency enforcement in order to protect consumers and ensure compliance with agency rules and standards. The need for such enhanced enforcement, of course, is much greater with respect to CBD products, given the extent of non-compliance in the CBD marketplace. While targeted enforcement may be helpful at the margins of the gluten-free marketplace to further enhance compliance and allow consumers even greater confidence in the accuracy of the gluten-free labeling, a major commitment to enforcement with respect to the CBD marketplace is necessary to recast how such products are presented and sold to consumers.

The need for adequate agency enforcement for CBD products is magnified by the current global health crisis and the fact that some CBD products make unsupported marketing claims in connection with COVID-19. In the current crisis, these claims are particularly dangerous. As consumer advocates have noted, "CBD carries potential risks . . . [n]ot one scintilla of credible scientific evidence indicates that CBD products prevent the spread of the coronavirus. Consumers need to know these facts."[192] As discussed above, the FDA has issued warning letters to sellers of products making such COVID-19 related claims. Continuing to identify and address such CBD products quickly should remain an agency priority, as the agency must still identify and address CBD products making claims to treat other serious diseases as well.

Challenges to agency enforcement for CBD products and gluten-free products differ in the key aspects of marketplace size and in the volume of non-compliant products. FDA enforcement with respect to gluten-free products faces a unique challenge: namely, in a marketplace of many compliant products, detecting those non-compliant products which may require testing to identify, and where only some types of products might be non-compliant, or even only some isolated units of certain products. This task is easier where the product is non-compliant as a result of facial misbranding. In such cases, non-compliant products may be detected based solely on an examination of product labeling without the need for analytical testing of the product's contents. In the case of unproven health claims relating to CBD, non-compliant products could also be detected by a review of product marketing materials or packaging, also without the need for product testing. FDA

192. Sally Greenberg & Thomas Gremillion, *Buyer beware: False medical claims about CBD and COVID-19*, THE HILL (May 18, 2020), https://thehill.com/opinion/healthcare/498292-buyer-beware-false-medical-claims-about-cbd-and-covid-19 [https://perma.cc/A4GG-Z764].

enforcement related to CBD products can be difficult, however, due to the sheer volume of non-compliant products on the marketplace.

Indeed, the FDA has recognized the need for increased agency enforcement with respect to CBD items. In 2020, the agency requested $5 million within its 2021 budget to allow for CBD-specific regulation and enforcement. The $5 million, specifically, was intended to "support regulatory activities, including developing policy," and to allow the FDA to "continue to perform its existing regulatory responsibilities including review of product applications, inspections, enforcement, and targeted research."[193] Four million dollars in new funding and eleven full time-employees were requested under the Food Safety budget in order to allow the FDA to support its work with respect to CBD products. The House Appropriations Committee approved the $5 million request, noting "its concern about the proliferation of foods and dietary supplements marketed in violation" of the Federal Food, Drug, and Cosmetic Act (FFDCA), "including products containing cannabis and cannabis-derived ingredients."[194] The House Committee "expect[ed] the FDA to continue to prioritize consumer-safety through application of the law[,]" as "[n]on-FFDCA compliant products continue to pose potential health and safety risks to consumers through unsubstantiated and misleading claims such as treating a wide-range of life-threatening diseases and conditions."[195] The need for heightened agency enforcement with respect to CBD items thus has been acknowledged as a key issue for the FDA.

IV. RECOMMENDATIONS FOR NOVEL PRODUCTS AND AREAS

A. Corporate Self-Enforcement

This section examines how firms can use available mechanisms to internally strengthen their commitment to compliance and ability to successfully achieve compliance with respect to CBD and gluten-free items and other novel products. This conceptual approach to compliance, focusing on the role of the industry actor as a proactive agent for marketplace change, stems from a view of a firm as a "law-abiding actor, struggling in good faith to comply with increasingly complicated and contradictory laws and regulations."[196] In such a compliance model, the commitment to compliance "flows from the firm's drive to

193. *Justification of Estimates for Appropriations Committees*, DEP'T OF HEALTH AND HUMAN SERVICES (2021), https://www.fda.gov/media/135078/download [https://perma.cc/EET6-FS3N].

194. Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, H.R. 116, 2021 Sess. (2021), https://appropriations.house.gov/sites/democrats.appropriations.house.gov/files/Ag%20Report%20received%207-2-20.pdf [https://perma.cc/Y5JY-HNJD].

195. *Id.*

196. Timothy F. Malloy, *Regulation, Compliance, and the Firm*, 76 TEMP. L. REV. 451, 454 (2003).

obey the law, sometimes called the 'compliance norm[,]'" which "relies upon the firm's capacity to monitor and control its own behavior independent of external government sanctions."[197] According to this theoretical model of compliance, once appropriate compliance measures with respect to novel products are clearly identified, companies will adopt those measures regardless of the state of the existing government enforcement policy.[198] The self-enforcement measures recommended within this section are also useful even if the law-abiding view of the firm is not viewed as dominant. One might subscribe instead to the model of the firm as a partially or wholly profit-maximizing entity that develops compliance measures only in direct response to the perceived risk of government enforcement. In that case, self-enforcement measures are still somewhat useful in the context of novel products. Because the nature of government regulation and extent of government enforcement may change quickly with respect to novel products, it can still be useful for the more profit-focused firm to anticipate and identify future government action in such areas through pursuing independent internal action.

Where the FDA has not historically fully enforced regulatory standards or restrictions applicable to novel product types, or where fully robust standards and restrictions do not yet exist, manufacturers or sellers have the ability to promote consumer health and safety by engaging in self-enforcement and more closely scrutinizing the nature of the products they sell, and the marketing used to promote them. There may be several types of benefits that could accrue to the company in doing so. For example, companies that prioritize internal corporate compliance, including adherence to federal food and drug regulations, are less likely to face agency enforcement if their products are more likely to be compliant with agency regulations as a result of robust corporate compliance measures. Even if such companies do have a compliance failure and face agency enforcement action as a result, the presence of a robust compliance function and the ability to demonstrate the strength of internal compliance to an agency can often result in more lenient agency treatment than the agency would accord to a company that showed a more widespread disregard for implementing compliance measures.[199]

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197. *Id.* at 455.

198. *Id.* ("Because the compliance norm relies upon the firm's capacity to monitor and control its own behavior independent of external government sanctions, in theory norm-based regulatory programs should elicit compliance even where the firm's activity is shielded from the regulator's gaze").

199. *See, e.g.*, U.S. Dep't of Justice Criminal Division, *Evaluation of Corporate Compliance Programs* (updated June 2020), https://www.justice.gov/criminal-fraud/page/file/937501/download [https://perma.cc/KH7S-9Q5M] at 1; *see also* Madeleine Giquinto & Cynthia Schnedar, *The Impact of DOJ's Evaluation of Corporate Compliance Programs on FDA-Regulated Products*,

This section therefore outlines certain lessons from the examples of gluten-free and CBD items that companies can use when considering how to conceptualize the compliance function and their compliance responsibilities with respect to novel products. These include understanding how to anticipate forthcoming regulatory standards where it might be reasonable to expect that the agency will take some action to either establish or change such standards in the near future. Also, it is important to recognize the existence of current legal frameworks and apply those requirements to the business of manufacturing, marketing, and selling novel products. Finally, companies can consider mechanisms to monitor and signal their commitment to compliance to both regulators and their consumers; for example, by engaging in a third-party certification process that verifies the quality and reliability of their novel products and any associated claims made in connection with those items.

B. Anticipating Regulatory Standards

The enactment of gluten-free labeling standards demonstrates that the FDA may certainly act to create regulatory standards and guidance where novel products emerge, even if the creation and enactment of those standards takes an extended period of time. Where there is a clear need for either heightened enforcement or the development of new regulatory standards, the FDA can be expected to eventually address those issues, even if the process is somewhat delayed due to the particular challenges of novel products.

Knowing that a regulatory standard will emerge, however, does not resolve the challenge whereby companies may have difficulty anticipating the full scope and nature of FDA rules before they are established. This presents a challenge to companies seeking to be compliant; they might not have the technical knowledge and expertise to understand how to best protect their consumers by balancing health concerns with business considerations. Under-investing in compliance might inadequately protect consumer health and safety. Conversely, over-investment in certain precautionary measures might make a firm less competitive while providing minimal marginal benefits to consumers. There might also be a misallocation of compliance resources,

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FOOD & DRUG LAW INST., https://www.fdli.org/2020/04/the-impact-of-dojs-evaluation-of-corporate-compliance-programs-on-fda-regulated-products/ [https://perma.cc/6PBQ-EGJA] ("at the Food and Drug Law Institute (FDLI) Enforcement, Litigation, and Compliance Conference in 2019, DOJ signaled that the 2019 DOJ Guidance should be of interest to companies who are regulated by the Food and Drug Administration . . . DOJ Deputy Assistant Attorney General David Morrel stated that the actions taken by the DOJ Consumer Protection Branch (CPB) in conjunction with FDA are 'all caused by failures of corporate compliance programs.' He went on to state that the CPB 'follows the same principles as the DOJ's Criminal Division of assessing compliance programs for charging and resolution purposes', announcing the emphasis DOJ will place on the 2019 DOJ Guidance when making decisions of whether to investigate, bring charges, or resolve cases brought under" the Food, Drug, and Cosmetic Act).

whereby firms might devote resources to measures that do not address those issues of novel products that have the greatest potential to affect human health and safety.

For example, before the 2013 enactment of regulatory standards with respect to gluten-free items, a major challenge for companies seeking to self-enforce their gluten-free products was considering how to use the term "gluten-free," absent a regulatory standard defining that term. Such manufacturers faced the burden of identifying the threshold level of gluten likely to provide medical benefits to consumers, a task for which they were perhaps not necessarily ideally suited in their capacity as product manufacturers rather than scientific or medical professionals. The lack of a clear standard also presented great challenges to the consumer in identifying which manufacturers had effectively self-enforced an appropriate definition of the term "gluten-free" and what that phrase actually meant as used by various manufacturers.

The process whereby the FDA established the gluten-free labeling rules might provide an illustrative example of how companies can anticipate various factors weighed in creating an appropriate regulatory standard. When selecting the appropriate regulatory threshold for gluten, comments to the proposed FDA rule containing the 20 ppm threshold (using an analytical method-based approach, rather than a safety assessment-based approach) raised four primary issues.[200] The FDA categorized these comments as follows:

- The potential impact of the choice of approach on the availability of foods that could be labeled "gluten-free";
- The potential impact on the health of individuals with celiac disease of the choice of approach for establishing a regulatory definition of "gluten-free";
- The availability of analytical methods to evaluate compliance and to enforce a regulatory definition of "gluten-free" at different levels; and
- The relationship between FDA's definition of "gluten-free" and that of international bodies.

The FDA, in its response to these comments, discussed its consideration of each of these factors in setting the gluten-free numerical threshold. Specifically, the FDA balanced the need to protect the health of most gluten-free consumers with a genuine medical need against the practical feasibility of mandating certain threshold levels. The agency examined how consumer welfare might also be affected by different numerical thresholds in terms of affecting the breadth of products available to consumers. The agency also considered its own

200. 78 Fed. Reg. 47,154 (Aug. 5, 2013).

ability to verify compliance with any rule eventually adopted. Finally, the FDA considered the examples and experiences of other jurisdictions and international bodies with respect to this issue.

The FDA recognized that "the food industry may be unable to consistently meet a standard" below 1 ppm for gluten in foods labeled as gluten-free, especially where such a method could not, in practice, be scientifically verified at the time of the enactment of the regulation.[201] The FDA recognized that "such an approach would result in the removal from the market of many products" that were labeled before the enactment of the regulation as containing less than 20 ppm of gluten, and would also "discourage the introduction of new foods labeled as 'gluten-free.'"[202] If a limit lower than the 20 ppm threshold were to be enacted, the FDA believed that consumer welfare would be reduced because "[l]imiting the availability of the number and variety of foods labeled 'gluten-free' would be detrimental to individuals with celiac disease who are already challenged by the complexities of adhering long term to a gluten-free diet."[203] The FDA also noted that "[t]he scientific research conducted thus far and the information presented in our Gluten Report support a conclusion that most individuals with celiac disease can tolerate food that contains variable trace amounts and concentrations of gluten."[204] Instead of requiring that the gluten-free limit be set below 20 ppm, the FDA considered the practicality of analytical verification, probable health effects on most consumers requiring gluten-free foods, and the impact that a lower gluten-free limit would have on the availability of consumer choice.

At the time the regulation was enacted, the standard adopted by the FDA was "similar, but not identical" to the definitions of gluten-free as set by the Codex Alimentarius Commission, the European Commission, and Canada.[205] Although each of those bodies generally set a standard very similar to the 20 ppm threshold, there was some variation in the allowed ingredients and permitted manufacturing processes. Further, Australia and New Zealand standards allowed "low gluten" and "very low gluten" claims, which the FDA declined to adopt.[206]

The FDA's consideration on the practical ability of the agency to detect violations of the adopted standard was not unique to the gluten-free labeling context. Indeed, the feasibility of methods to evaluate and enforce compliance has been recognized by commentators to be

201. *Id.*
202. *Id.*
203. *Id.*
204. *Id.* (citing 76 Fed. Reg. 46,671 (Aug. 3, 2011) at 674-675).
205. *Id.*
206. *Id.*

important to effective regulation and compliance in general. Verifiability, namely "the capacity to monitor compliance with regulatory compliance . . . is a critical component of effective regulation."[207]

Based on the primary categories of comments considered by the FDA in setting the gluten-free threshold, companies dealing with other novel product types that are likely to be subject to future regulation can reasonably expect that the FDA might enact regulations based on consumer health and safety, the potential impact of regulation on product availability, the feasibility of analytical methods to evaluate and enforce compliance, and the similarity of proposed U.S. regulation to standards set by international organizations or in other jurisdictions. Depending on the relevance and applicability of each of these factors with respect to the particular novel food or drug product, a seller or manufacturer of such a product might reasonably expect the FDA to rely on these factors to develop an applicable regulatory standard.

C. Recognizing Existing Rules

While businesses try to anticipate new regulatory standards and enforcement policies for novel product areas, they must also be cognizant that there may well be already-existing laws and regulations that might apply to their products. Such is the case for CBD items bearing unproven health claims.[208] In such instances, the FDA uses the existing procedure of warning letters to notify companies that their products claim to treat serious diseases without the requisite support. In the case of CBD items and unproven health claims, although the product type is novel, the relevant rules and mechanisms for agency enforcement are not. While enforcement discretion might vary depending on the particular administration or evolve over time as CBD becomes more commonly accepted, the underlying set of standards is one that has been applied to numerous types of products over an extended period of years.

A common pitfall for a CBD manufacturer or seller seeking to ensure compliance, then, is not that the company will fail to anticipate a

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207. David L. Markell & Robert L. Glicksman, *A Holistic Look at Agency Enforcement*, 93 N.C. L. REV. 1, 18 (2014).

208. For example, the FTC noted in connection with the announcement of its Operation CBDeceit that "the sweep shouldn't come as big news to members of the CBD industry . . . The message to marketers has been consistent: The same substantiation principles the FTC has applied to health claims for close to 50 years apply to similar claims for CBD products. Companies that represent expressly or by implication that what they sell can prevent, treat, or cure serious medical conditions will be held to the highest substantiation standards and marketers can expect careful scrutiny of those promises." Lesley Fair, *One thing marketers of CBD products need to know right now*, FED. TRADE COMM'N (Dec. 17, 2020), https://www.ftc.gov/news-events/blogs/business-blog/2020/12/one-thing-marketers-cbd-products-need-know-right-now [https://perma.cc/89M3-QR4L].

new regulatory standard, but rather, that it will fail to recognize that its products are fundamentally similar to and governed by the same set of rules as other products that make health claims. One advantage of the gluten-free labeling standards was, perhaps, the novelty of the standard and the one-year period between the announcement of the rule and date it became effective. A complete lack of standards for gluten-free labeling in the marketplace became a clearly defined numerical standard, heralded by numerous industry and consumer publications and other media outlets.[209] With respect to CBD products, however, the long-existing rules of unproven health claims as applied to CBD items did not make news in the same way as the new numerical gluten-free standard. Rather, news items relating to this issue were often generated only as a result of agency enforcement actions.[210]

Therefore, novel products that generate new regulatory standards may benefit from increased publicity at the time those rules are announced, while novel products subject to already-existing rules might require well-publicized enforcement measures to be undertaken before product sellers become more generally cognizant of the most relevant rules that already exist and that govern the manufacture, sale, and marketing of their novel products. Those novel product sellers that take proactive steps to identify already-existing rules relevant to their products will be better able to anticipate and avoid potential agency enforcement action through ensuring compliance of their products. Ben & Jerry's is an example of a manufacturer of a potential novel product (in this case, CBD-infused ice cream) who successfully identified an existing applicable regulatory framework and conformed to its

209. *See, e.g.*, Mary Clare Jalonick, *FDA defining what 'gluten-free' means on food labels*, NBCNEWS.COM (Aug. 2, 2013), https://www.nbcnews.com/healthmain/fda-defining-what-gluten-free-means-food-labels-6C10824391 [https://perma.cc/3DVD-JQ5X]; Associated Press, *Gluten-free labeling standards kick in*, HOUSTON CHRONICLE (Aug. 5, 2014), https://www.houstonchronicle.com/business/article/Gluten-free-labeling-standards-kick-in-5670837.php [https://perma.cc/2WUJ-HBN2]; Rachel Begun, *Best Practices for Preparing, Labeling and Serving Gluten-Free*, FOOD MANAGEMENT (Oct. 24, 2014), https://www.food-management.com/blog/best-practices-preparing-labeling-and-serving-gluten-free [https://perma.cc/F2DS-ZQL4]; *Gluten-Free Labeling Rule in Effect Today*, SPECIALTY FOOD ASSOCIATION, INC. (Aug. 5, 2014), https://www.specialtyfood.com/news/article/new-gluten-free-labeling-rule-go-effect/ [https://perma.cc/H3BA-TBMQ]; Dave Bloom, *FDA Announces New Rules for Gluten-Free Labeling*, SNACKSAFELY.COM (Aug. 2, 2013), https://snacksafely.com/2013/08/fda-announces-new-rules-for-gluten-free-labeling/ [https://perma.cc/8W5X-5DGP].

210. *See, e.g.*, Sam Wood, *FTC threatens action against CBD companies making bogus health claims*, PHILADELPHIA INQUIRER (Sept. 10, 2019), https://www.inquirer.com/business/cbd-cannabidiol-ftc-warns-companies-claiming-unfounded-unproven-health-benefits-20190910.html [https://perma.cc/VH9L-LMDJ]; Angelica LaVito, *FDA issues warning to Curaleaf for "illegally selling" CBD products with "unsubstantiated health claims"*, CNBC.COM (July 23, 2019), https://www.cnbc.com/2019/07/23/curaleaf-gets-warning-from-fda-for-unsubstantiated-cbd-claims.html [https://perma.cc/6XU4-BVG7]; Dan Nosowitz, *FDA Tells CBD-Sellers to Stop Touting Unproven Health Claims*, MODERN FARMER (Aug. 7, 2019), https://modernfarmer.com/2019/08/fda-tells-cbd-sellers-to-stop-touting-unproven-health-claims/ [https://perma.cc/3VDW-7ED9].

restrictions, thereby avoiding a regulatory violation. Ben & Jerry's has stated that it is "open to bringing the CBD-infused ice cream to your freezer as soon as it's legalized at the federal level[,]" and submitted a comment to the FDA in support of the legalization of CBD-infused food and beverages.[211] The company also provided information to its customers as to how to submit similar comments, and allowed customers to sign up for updates on the availability of CBD-infused ice cream.[212] In this manner, Ben & Jerry's posted information with the potential to generate consumer interest in its possible novel product, while recognizing the existing regulatory framework in place and acting in compliance with its restrictions by not actually producing or selling CBD-infused ice cream while it remains illegal to be sold in interstate commerce.[213]

CBD sellers also face the added burden of ensuring that their products comply not only with the federal standards regarding unproven health claims, but also the patchwork of state laws governing the sale of CBD products. Where state regulations apply in addition to federal rules, as is the case for CBD, manufacturers and sellers must identify all applicable laws and regulations and create a product manufacturing and marketing system that takes all of those requirements into account. Moreover, those firms must also anticipate changes to those state laws that might affect their products. State rules and policies regarding CBD items can change rapidly. For example, in 2020, a new registration requirement to sell CBD edibles took effect in Florida.[214] Likewise, in late 2020 the New York State Department of Health issued proposed regulations that would "creat[e] a licensing framework for cannabinoid hemp processors and retailers," and would also establish "basic manufacturing, packaging and labeling and laboratory testing standards."[215]

In the context of novel products more generally, where such products are subject to state regulation, and where a single federal regulatory standard does preempt such rules, manufacturers and sellers of novel products must devote adequate resources to ensuring that they understand and are in compliance with all applicable legal

211. *CBD Ice Cream is (Maybe, Hopefully) Coming to a Freezer Near You!*, BEN & JERRY'S (May 30, 2019), https://www.benjerry.com/whats-new/2019/05/cbd-statement [https://perma.cc/H5U7-XRXT].

212. *Id.*

213. *See also* Edware Helmore, *Ben & Jerry's announces plans to make CBD-infused ice-cream*, THE GUARDIAN (May 30, 2019), https://www.theguardian.com/food/2019/may/30/ben-and-jerrys-cbd-ice-cream-legalized-federal-level [https://perma.cc/59SU-VGRV].

214. Dara Kam, *CBD products in Florida governed by new rules*, SOUTH FLORIDA SUN-SENTINEL (Jan. 6, 2020), https://www.sun-sentinel.com/news/politics/fl-ne-nsf-fried-cbd-regulations-20200106-zfxmwkzlwjfrpf2oudkc3gjexm-story.html [https://perma.cc/7L2E-QJCP].

215. *Governor Cuomo Announces Proposed Regulations for Cannabinoid Hemp Products*, NEW YORK STATE (Oct. 28, 2020), https://www.governor.ny.gov/news/governor-cuomo-announces-proposed-regulations-cannabinoid-hemp-products [https://perma.cc/R6PW-7PHQ].

requirements. Thus, the challenge of identifying and monitoring the existing legal framework is not limited to applicable federal regulations; manufacturers and sellers of novel products must also consider state or even local provisions that might govern the sale and marketing of their products.

D. Monitoring and Signaling Product Quality

With respect to both CBD products and packaged food items labeled as gluten-free, companies face the challenge of monitoring product quality (for example, ensuring that CBD products do in fact contain CBD, or that gluten-free-labeled products do not exceed the gluten threshold levels or contain prohibited ingredients).[216] They also face the challenge of signaling to consumers the reliability of their products, especially in a crowded marketplace where other sellers might be making false claims about the nature of their products. For example, CBD product sellers who conform to FDA standards and refrain from making unproven health claims might in fact be at a business disadvantage in a marketplace where such claims are commonly used by other sellers to promote similar products. The compliant CBD seller therefore would be faced with the additional challenge of signaling to the consumer the nature of its product in an accurate way that attracts the consumer's attention in a crowded marketplace. A compliant manufacturer might also face increased costs as a result of their commitment to maintaining reliable manufacturing processes, while facing competition from other manufacturers who might choose not to devote the same resources to ensuring that their products remain safe and compliant. A challenge for the compliant manufacturer exists in how to effectively transmit information to consumers about their product quality in order to regain some of those compliance costs through consumer sales.

As discussed earlier in this Article, some manufacturers of gluten-free products choose to signal their commitment to self-enforcement by labeling their items with third-party certifications, such as the "Certified Gluten-Free" symbol. Such marks signal to the consumer that beyond whatever enforcement the FDA might be taking with respect to gluten-free items, another independent organization is evaluating, testing, and certifying these products as genuinely gluten-free. Similar independent certifications could provide assurances to consumers of CBD products that CBD items do, in fact, contain CBD and do not contain prohibited substances such as THC. Indeed, LegitScript announced a certification program for CBD products and CBD websites

216. For gluten-free items, this challenge was of course of a much greater magnitude before the announcement and effective date of the 20 ppm threshold adopted as part of the legal definition of "gluten-free."

in 2019.[217] The certification program offers potential benefits to manufacturers and retailers that include "[p]rov[ing] [y]our [p]roduct [q]uality[,]" "[s]tand[ing] [o]ut [f]rom the [c]rowd[,]" and "[g]ain[ing] [a]pproval [f]rom a [t]rusted [t]hird [p]arty."[218] The National Industrial Hemp Council (NIHC) in November 2021 announced plans for a pilot program that would allow CBD item sellers to label their products as complying with NIHC standards.[219]

While independent certifications would still not allow sellers of CBD products to make medical claims in their marketing, they might provide a useful signaling device to consumers about the commitment of CBD product manufacturers to creating a uniform product that contains the substance it purports to. The challenge, however, lies in creating a single or a small number of certifications that will be recognized by consumers as reliable in providing useful information about the true content of a CBD product. A plethora of independent certifications available, or the availability of unreliable certifications, might only serve to further obfuscate consumer decision-making.

The potential value of third-party certifications could also be useful to sellers of novel products more generally. The ability of such certifications to affect consumer behavior would likely depend on a number of factors, including the familiarity of the consumer with the particular certification, the reliability of the particular certification, the nature of the product and the particular risks to the consumer, and the consumer's knowledge of those risks. Firms involved in selling novel products might find it worthwhile to consider the potential benefits of third-party certifications, especially in those contexts where there is either a present lack of regulatory standards or unclear agency enforcement policy with respect to their items.

V. RECOMMENDATIONS FOR NOVEL PRODUCTS AND AREAS: AGENCY ACTION AND ENFORCEMENT

This Part examines how regulatory compliance with respect to new and evolving products can be promoted through direct agency action, such as by standard-setting, adopting clearer enforcement policies, or choosing to enforce more robustly with respect to product types for which relatively low levels of resources have historically been devoted

217. LegitScript Folks, *LegitScript Announces New CBD Certification Program*, LEGITSCRIPT (June 27, 2019), https://www.legitscript.com/blog/2019/06/legitscript-announces-new-cbd-certification-program/ [https://perma.cc/NA4F-LZM5]; *CBD Certification*, LEGITSCRIPT, https://www.legitscript.com/service/certification/cbd/ [https://www.wyden.senate.gov/imo/media/doc/011519%20FDA%20CBD%20Hemp%20Letter.pdf].

218. *Id.*

219. National Industrial Hemp Council, *NIHC Announces Effort to Strengthen Testing Standards, Labels for CBD*, PR NEWSWIRE (Nov. 16, 2021), https://www.prnewswire.com/news-releases/nihc-announces-effort-to-strengthen-testing-standards-labels-for-cbd-301425043.html [https://perma.cc/NL9Z-ELXS].

to enforcement. This Part also proposes recommendations for increased enforcement with respect to both CBD and gluten-free items—at the margins for gluten-free products, and in a more fundamental shift for CBD items.

The examples of CBD items and gluten-free products demonstrate varying degrees to which enforcement must be used in order to achieve widespread industry compliance with agency standards. Gluten-free products, after adoption of a governing regulatory standard, often conform to meet that standard. In contrast, many CBD products are widely marketed with impermissible health claims or are sold in the form of food and beverages with CBD additives, in violation of FDA rules. A regulatory standard alone is therefore helpful, but not sufficient, to ensure company self-policing and adherence to agency rules. This Part therefore calls for increased agency enforcement with respect to these and other novel product types, although the amount of enforcement necessary will vary depending on the severity of noncompliance within the particular marketplace.

A. CBD Items

Increased and more widespread agency enforcement with respect to CBD items is particularly necessary to enforce the prohibition against marketing items claiming to treat serious diseases with unproven health claims. As one newspaper editorial board has argued, "[t]he FDA should squelch false claims of the benefits of CBD until proven in scientific testing with stronger enforcement actions than a warning letter."[220] Stronger enforcement by the FDA might also help producers of high-quality products adequately signal to consumers the safety and reliability of their products, by removing lower-quality products from the marketplace. The same editorial argued that "[l]egitimate, high quality producers would benefit from regulation to push cheap, shoddily processed and fake products out of the market."[221]

The presence of CBD-infused foods and drugs in interstate commerce also provides a strong case for agency enforcement, due to the blanket prohibitions in place for such products. Alternatively, if the agency reaches a determination that it does not wish to pursue increased enforcement against such products, relevant laws and regulations should be amended to provide a legal avenue for the sale of CBD-infused foods and beverages in interstate commerce. Such a change to

220. Editorial Board, *CBD regulation: Consumers, industry would benefit from standards*, PITTSBURGH POST-GAZETTE (May 2, 2020 https://www.post-gazette.com/opinion/editorials/2020/05/02/CBD-regulation-Consumers-industry-would-benefit-from-standards/stories/202003070024 [https://perma.cc/9P9J-N3ZB].

221. *Id.*

the existing legal framework, however, should only take place if and when supported by scientific evidence, in order to ensure the protection of consumer health and safety.

Some lawmakers have argued for the modification of the existing legal framework for some types of CBD products, rather than the approach of increased agency enforcement. For example, after the passage of the Hemp Farming Act, its authors (Senator Ron Wyden and Senator Jeffrey Merkley) issued a letter in January 2019 urging the Commissioner of the FDA to "[i]mmediately begin updating regulations for hemp-derived CBD and other hemp-derived cannabinoids, and give U.S. producers more flexibility in the production, consumption, and sale of hemp products."[222] They specifically asked, in part, what lawful pathways were currently available for the introduction of *Cannabis sativa* L. and its derivatives in food, beverages, or dietary supplements, and whether there were circumstances that existed, or possible regulations that could be issued, for allowing *Cannabis sativa* L. in food, beverages, or dietary supplements. Proposed legislation (the CBD Product Safety and Standardization Act) was introduced in November 2021 to allow FDA to regulate CBD as a food ingredient.[223]

Given the current lack of extensive scientific research into the safety and effects of CBD, this Article proposes that increased enforcement within the existing regulatory framework is the preferable solution to a fundamental change in either the types of CBD products permitted or the types of claims the manufacturers and sellers of those products can legally make. In the alternative, creating a pathway to legalization of CBD in foods and drinks in interstate commerce could be a viable choice at some point in the future, depending on the development of research as to the potential benefits and/or risks of such products. Certain health claims could also be permitted if sufficient scientific evidence is developed to support them.[224] What most undermines regulatory authority, consumer protection, and the ability of

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222. Letter from Senator Ron Wyden to Commissioner Scott Gottlieb of the U.S. Food and Drug Administration (Jan. 15, 2019), https://www.wyden.senate.gov/imo/media/doc/011519%20FDA%20CBD%20Hemp%20Letter.pdf [https://perma.cc/3ETD-6XNR].

223. Rep. Kathleen Rice, *Rice Leads Introduction of Bipartisan CBD Product Safety and Standardization Act* (Dec. 2, 2021), https://kathleenrice.house.gov/news/documentsingle.aspx?DocumentID=1759.

224. FTC Commissioner Christine S. Wilson, in a 2020 concurring statement regarding the FTC's six settlements with CBD sellers, expressed her "hope that the [FTC]'s actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products[,]" and urged the FTC, consistent with prior statements by other Commissioners, to "be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market." Christine S. Wilson, *Concurring Statement of Commissioner Christine S. Wilson*, FEDERAL TRADE COMM'N (Dec. 17, 2020), https://www.ftc.gov/system/files/documents/public_statements/1584922/2023047cbdwilsonstatement2.pdf [https://perma.cc/3P5P-ED7W].

industry to clearly understand their duties under the law, however, is a situation similar to that which currently exists—namely, the existence of regulatory prohibitions against CBD-infused foods and beverages and against products (including CBD items) making unproven health claims, with no robust, coordinated agency response to attempt to remove such items from the market en masse.

For CBD products, in addition to federal standards, there are also a variety of state laws that govern the sale of such products, as discussed earlier within this Article. Changes in federal regulatory standards or to agency enforcement policy can be considered in conjunction with existing state frameworks of law, and in conjunction with state enforcement policies. Due to the differences in state laws and regulations, consumer health and safety can perhaps be best promoted through a single set of effective federal standards and enforcement policies. Robust federal standards and enforcement can also be helpful for industry actors were state regulations to be modified to conform to those standards, and the patchwork of state provisions were eliminated or harmonized in response to the example of federal regulation. Before a repeal of various state laws governing CBD products can be considered largely beneficial, however, CBD products must be subject to adequate regulation and supervision at the federal level. State laws, while inefficient for product manufacturers and sellers to comply with, may at the current time serve the important end of protecting the public interest while federal enforcement policies are being finalized and fully implemented.

B. Gluten-Free Products

The adoption of the gluten-free labeling standard has improved the ability of consumers to rely on gluten-free labeling by empowering them to understand exactly what standard a company is expected to adhere to in placing a gluten-free label on a packaged food item. Even in the absence of a strong pattern of agency enforcement, the studies mentioned in Section II of this Article suggest that products do often conform with the regulatory standard. That is not to say, however, that the gluten-free labeling regime or compliance with the announced standard is perfect. The potential opportunities for improvement with respect to gluten-free labeling have now largely shifted from the need for the agency to set an applicable regulatory standard to the need for the agency to develop a consistent, robust enforcement strategy that will ensure an even greater degree of product compliance with the standard governing gluten-free claims. Such enforcement would help ensure that those food items that do not meet regulatory standards are caught quickly and removed from the marketplace, so that they do not threaten consumer health or undermine consumer confidence in the regulatory standard.

Such increased enforcement is justified, especially given the fact that gluten-free labeling is voluntary. Food products that would qualify for gluten-free labeling under the regulatory standard do not, in fact, need to be labeled as such; the decision to do so is the choice of the product manufacturer or seller.[225] Sellers of packaged gluten-free food items are often able to sell those items at a premium compared with similar items not labeled as gluten-free.[226] Increased agency enforcement with respect to gluten-free items, where necessary to protect consumer safety and increase consumer trust in the reliability of the gluten-free label, would perhaps be less likely to affect the availability of gluten-free items when such an increased enforcement cost to the manufacturer or seller is weighed against the increased profit available as a result of using the gluten-free label.

Input from consumer groups, as well as adverse event reports directly from consumers, can be valuable tools to efficiently identify those products that fail to meet the regulatory standard. An FDA enforcement policy to ensure more complete compliance with the gluten-free labeling standard should encompass the prompt investigation and response to products that are the subject of consumer adverse event reports. This is especially important where non-compliant products might not uniformly fail to meet the numerical gluten threshold, for example, where inadequate manufacturing processes lead to the contamination of only a portion of batches or lots produced by the manufacturer. The full use of adverse event reports and other reports from consumers can help identify those products that pose a threat to consumer health without requiring problems to first be detected through the use of extensive agency testing.

C. Novel Products Generally

The issue of how to best promote compliance in the realm of novel products may be informed by the more general question of how promoting compliance is achieved in the context of food and drug products, or in the corporate realm more generally. "Compliance is a system that is typified by constant change, activity, or evolution[,]" including with respect to the emergence of novel regulatory and enforcement strategies around novel product types.[227]

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225. U.S. Food & Drug Admin., *supra* note 125 ("Are all FDA-regulated foods that meet the definition of "gluten-free" required to be labeled gluten-free? No. The regulation establish [sic] requirements for the voluntary use of "gluten-free" claims?")

226. Anne R. Lee et al., *Persistent Economic Burden of the Gluten Free Diet*, 11 NUTRIENTS, 3 (2019) (finding that the overall cost of gluten-free products was 183% more expensive than wheat-based counterparts).

227. Robert C. Bird and Stephen Kim Park, *Turning Corporate Compliance into Competitive Advantage*, 19 U. PA. J. BUS. L. 285, 291 (2017).

As for gluten-free products, implementing clear and science-based standards can be helpful for companies to clarify their compliance responsibilities and understand how they can ensure that their products promote the welfare of consumers. A federal standard for items sold in interstate commerce can be helpful in allowing product manufacturers to develop their products for sale nationwide. Where instead consumers face a patchwork of state regulations and no clear federal standard, as is often the case for CBD products, product manufacturers and sellers may have a hard time understanding their compliance duties, monitoring changes in state law, and ensuring that their products are made, marketed, and sold in such a way as to satisfy a variety of state laws. A robust federal standard can therefore provide sellers with a helpful framework around which to develop their compliance strategy for novel products.

Moreover, developing clear and consistent enforcement policies should certainly be an agency priority. "Making compliance work requires viewing compliance decisions through the lens of risk."[228] Where the principal mechanism for consumer protection lies in agency action, agency enforcement is key to reframing the industry understanding of risk around novel product types; thus, the legal risk of non-compliance becomes a greater factor in the compliance analysis, in addition to the existing reputational and moral risks of causing consumer harm. If facing a heightened enforcement regime, companies may be more fully incentivized to adequately monitor their products and marketing to attempt to reduce the likelihood of compliance failures. A common view of the firm as a compliance actor conceptualizes "the firm as a rational profit-maximizer, obeying the law only when it is in the firm's best economic interest to do so. Thus, violations occur when the perceived benefits of noncompliance exceed the anticipated cost of sanctions."[229] Thus, "[t]he rational profit-maximizer view typically leads to the use of traditional enforcement techniques; namely, extensive government monitoring and inspections coupled with penalties for observed violations."[230]

Further, a more robust enforcement regime would better put companies on notice of the types of compliance failures and product or labeling shortcomings that will be most likely to trigger agency action. Publicity around stronger, more coordinated agency enforcement could foreclose companies' claims that they were not aware of agency enforcement, or that the practical effect of regulatory language was unclear. A consistently applied enforcement policy can also reduce the burdens on compliant manufacturers and sellers who face competition

228. *Id.* at 297.

229. Malloy, *supra* note 196, at 453.

230. *Id.* at 454.

from non-compliant sellers who might save costs by devoting fewer resources to ensuring product quality and may unfairly gain market share by selling products based on unsupported health claims.

CONCLUSION

Companies seeking to ensure their compliance in these and other developing regulatory areas should be aware that levels of agency enforcement may be subject to change, and that an initial lack of agency response may not be indicative of future trends. Indeed, the examples of gluten-free labeling and CBD products discussed in this Article indicate the FDA will act to fill a regulatory vacuum, even if that response takes an extended period of time to announce and enact. Gluten-free labeling and CBD regulation also demonstrate that the agency is significantly likely to take action where the products to be regulated demonstrate a significant and/or growing market segment.

The example of gluten-free labeling shows that new regulatory structures can develop with respect to innovative products. Indeed, gluten-free labeling is an example of a successful regulatory change that improves the safety and well-being of those consumers who depend on accurate gluten-free labels. There certainly remains some room for improvement of agency enforcement against those products that do not comport with the regulatory standard. Overall, however, the gluten-free labeling regime is a positive development for consumer welfare and certainly represents an improvement over the pre-regulatory state of affairs.

CBD regulation, and agency enforcement against violative CBD products, has further to go in terms of protecting consumer safety and welfare. While the FDA has issued a number of warning letters against manufacturers and sellers improperly marketing their CBD products, similar products with equally impermissible claims remain widely available.

Apart from the issues of regulatory standard-setting and enforcement, CBD products remain susceptible to unproven claims because their potential medical benefits have not been fully researched. This Article does not take a position as to whether the optimal strategy for the greatest public good is to more fully liberalize the interstate sale and marketing of CBD products, or whether the public interest would be better served by the removal of non-compliant products from the marketplace through increased agency enforcement. That is because the scientific research does not exist yet with respect to the benefits and risks to human health resulting from the use of such products. When there is more robust scientific evidence to either support or deny the claims made by the manufacturers and sellers of CBD products, and the public becomes generally aware of those findings and the potential medical value of such products, there might be less room in the

marketplace or consumer tolerance for unproven claims. At the current time, consumers rely on anecdotal evidence or product marketing, instead of scientific research, when deciding to purchase and use CBD products for their medical conditions. Increased research on the effects of CBD on human health would aid the work of the FDA in protecting consumer health and safety.

With respect to gluten-free products, areas for improvement outside the regulatory context lie not principally in identifying the benefits to these products themselves, but instead to identifying the consumers who would benefit from their use. It is estimated that around 97% of celiac patients in the United States remain undiagnosed;[231] moreover, celiac cases in the United States have "doubled every 15 years since 1974."[232] As a growing percentage of celiac patients are diagnosed in the future, the importance of a reliable regulatory standard supported by effective enforcement will grow. The growth in consumer interest and purchasing of both CBD and gluten-free items further indicates that FDA enforcement will continue to be of importance in each of these areas in the year ahead. While the FDA has taken great strides in defining the regulatory standard for gluten-free labeling, there is room for more effectively promoting consumer health and safety through regulatory enforcement of gluten-free labeled items. Sellers and manufacturers of novel food and drug products, and regulators tasked with the oversight of such items, can use lessons learned from the regulation of CBD and gluten-free items to guide their work in the future.

231. *Celiac Disease Facts and Figures*, UNIVERSITY OF CHICAGO MEDICINE CELIAC DISEASE CENTER, https://www.cureceliacdisease.org/wp-content/uploads/341_CDCFact-Sheets8_FactsFigures.pdf [https://perma.cc/A6US-EJ58].

232. University of Maryland Medical Center, *Celiac disease rate is growing, particularly among elderly, study reveals*, SCIENCEDAILY (Sept. 27, 2010), https://www.sciencedaily.com/releases/2010/09/100927083811.htm [https://perma.cc/4Y6F-5BL6].