Debevoise In Depth

Private Equity Guide to Consumer Product Investing Under the Trump Administration: Food and Drug Administration (FDA) Developments

April 18, 2019

Overview

The Food and Drug Administration ("FDA") launched a number of new initiatives affecting consumer product companies under the leadership of Commissioner Scott Gottlieb during the first two years of the Trump administration. These initiatives impact a wide range of FDA-regulated consumer product categories, including foods, dietary supplements, cosmetics, over-the-counter ("OTC") drugs, e-cigarettes, and digital health products. It is therefore critical for private equity sponsors seeking to invest in consumer product companies to understand the impact of recent regulatory developments in order to identify the most promising opportunities.[1] Over the past two years, FDA has in many cases moved to lower regulatory burdens and encourage innovation, while other initiatives have increased regulatory oversight.

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FDA is currently confronting an inflection point. On March 5th, 2019, Commissioner Gottlieb announced his resignation. This announcement surprised stakeholders, as Gottlieb has been viewed as an unusually effective, fair and politically savvy FDA commissioner. Ned Sharpless, former director of the National Cancer Institute, became Acting FDA Commissioner on April 5th. Sharpless was reportedly Gottlieb's choice for the position, and we therefore do not expect Gottlieb's departure to dramatically alter agency policy. The longer-term effect of his departure, however, will depend on who President Trump nominates as permanent FDA Commissioner.

In addition to Gottlieb's departure, the recent election may also impact the consumer product regulatory landscape. The Democrats regained control of the House of Representatives at the beginning of 2019, resulting in a divided Congress. Although certain consumer product legislative initiatives are bipartisan (including pending

[1] This is the firm's second article exploring the impact of FDA developments under the Trump Administration on private equity investments. The first article addressed developments affecting drugs, biologics, and medical devices. Andrew L. Bab, Jennifer L. Chu, Kevin Rinker, Paul D. Rubin and Melissa B. Runsten, *Private Equity Guide to Life Sciences Investing Under the Trump Administration* (Mar. 15, 2018), https://www.debevoise.com/insights/publications/2018/03/private-equity-guide-to-life-sciences.

legislation that would reform the regulatory regimes for cosmetics and OTC drugs), the Democratic takeover of the House may lead to increased FDA oversight. For example, a number of Democratic members of Congress have questioned FDA's actions on digital health, expressing concern that expediting the entry of certain products to the market could result in safety tradeoffs. On the other hand, many Democrats in Congress have been supportive of Gottlieb's recent statements criticizing segments of the dietary supplement industry.

Despite these developments, many consumer product market trends—including the increasing importance of online retail sales, personalization and digital health, and products promoted as healthy, fresh, clean, and natural—are expected to continue unabated. In addition, hemp-related ingredients (including cannabidiol ("CBD")) are trendy additions to cosmetics, dietary supplements, and foods, based in part upon the passage of the Agriculture Improvement Act of 2018 (the "2018 Farm Bill"). An understanding of FDA's response to each of these trends—along with a broader understanding of where regulatory policy may head in the future—is essential for private equity sponsors seeking to invest in the consumer product space.[2]

This article provides an overview of FDA and legislative developments affecting consumer product investing during the first two years of the Trump administration, predicts future developments, and indicates how private equity funds may capitalize on the current regulatory landscape. The article is divided by product category: foods and dietary supplements, cosmetics, e-cigarettes and tobacco products, OTC drugs, and digital health products (*e.g.*, wearables and mobile medical apps).

Although this article focuses on FDA developments, private equity funds and investors should also closely evaluate the impact of actions by other regulatory agencies on consumer product investment opportunities, particularly actions by the Federal Trade Commission ("FTC") and Consumer Product Safety Commission ("CPSC").[3] In addition,

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[2] FDA's ability to issue significant guidance documents may be curtailed due to the release of a new memorandum by the Office of Management and Budget ("OMB") on April 11, 2019, which reiterates the requirement for "major" rules and guidance documents to be reviewed by the OMB Office of Information and Regulatory Affairs ("OIRA") prior to publication. The requirements imposed by this memorandum go into effect on May 11, 2019. OMB, Memorandum for the Heads of Executive Departments and Agencies (April 11, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-14.pdf.

[3] The FTC regulates consumer product advertising, and the CPSC, as a general rule, regulates consumer products not regulated by FDA. The FTC continues to target dietary supplement and cosmetic companies based upon alleged false advertising and has even investigated companies selling FDA-cleared OTC medical devices. *See, e.g.*, FTC Letter to TRIA Beauty, FTC File No. 142-3162 (July 31, 2015), https://www.ftc.gov/system/files/documents/closing_letters/nid/150731triabeauty.pdf. The FTC has five new commissioners who have expressed interest in expanding the range of remedies pursued in enforcement actions challenging false advertising. In addition, the CPSC has been far more aggressive in recent years pursuing criminal and civil penalties against consumer product companies (and responsible corporate officers) for, among other things, failing to report defects to the CPSC as required by Section 15(b) of the Consumer Product

because consumer product companies must craft their own claims (as FDA does not, as a general rule, authorize any consumer product safety or efficacy claims), these companies are particularly susceptible to class action lawsuits and challenges by state attorneys general based upon alleged dissemination of deceptive claims. Competitors also monitor questionable claims, leading to a proliferation of false advertising lawsuits brought by competitors based upon Section 43(a) of the Lanham Act.[4] All of these areas should be routinely assessed when evaluating consumer product companies for potential investment opportunities.

Food and Dietary Supplements

FDA is largely responsible for ensuring the safety and quality of the U.S. food supply.[5] The agency also regulates dietary supplements as a subcategory of food pursuant to the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). Food and dietary supplement companies may sell their products without pre-approval from FDA, providing the ability to innovate as consumer tastes and preferences change. We address below a number of high-profile issues currently impacting the food/dietary supplement investment environment.

Cell-Based Meat

Cell-based, or lab-grown, meat is an emerging sector. Companies harvest and multiply animal cells in an effort to create meat products that do not require the slaughter of animals. FDA and USDA initially disagreed over jurisdiction of this promising technology. USDA believed that cell-based meat is a meat product and within its jurisdiction. FDA believed that because the manufacture of these products did not require the slaughter of animals, they were food products under FDA's jurisdiction.

In November 2018, after months of deliberation and public meetings, the two agencies jointly announced a plan to share responsibility for regulating cell-based meats. An agreement released in March 2019 formalized the regulatory framework.[6] Under the

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Safety Act ("CPSA"). *See, e.g.*, U.S. Department of Justice, Two Corporate Executives Indicted in First-Ever Criminal Prosecution for Failure to Report Under Consumer Product Safety Act (Mar. 29, 2019), https://www.justice.gov/opa/pr/two-corporate-executives-indicted-first-ever-criminal-prosecution-failure-report-under. The FTC and the CPSC have been evaluating their roles in enforcing against consumer product companies involved in the "Internet of Things" ("IoT"), a term used to refer to Internet-connected products.

4 *See* David H. Bernstein & Bruce P. Keller, The Law of Advertising, Marketing and Promotions (2018).

5 The United States Department of Agriculture ("USDA") regulates meat, poultry, and certain egg products.

6 Formal Agreement between the U.S. Department of Health and Human Services Food and Drug Administration and U.S. Department of Agriculture Office of Food Safety (Mar. 7, 2019), https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aacdec1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES.

framework, FDA will regulate cell collection and growth. After the cells are harvested, USDA will take over, regulating the production and labeling of food products derived from the cells.[7] This plan is intended to leverage each agency's strengths while fostering the commercial development of innovative food products. Specifics on how the plan will work in practice have yet to be announced. Complicating the issue further are actions by a handful of states to regulate the labeling of these products. For example, a number of states have recently passed laws prohibiting cell-based meat products from being labeled as "meat."

Takeaway: The joint agreement between FDA and USDA provides clarity for a growing number of companies developing cell-based meat products, paving the way for the sector's growth. Investors should anticipate guidance from both agencies on how the day-to-day regulatory oversight will work to determine the regulatory burdens of developing and manufacturing these novel products.

Food Labeling Changes: Nutrition Facts Panels, Bioengineered Food Disclosures, and Dairy Labeling

In May 2016, FDA announced a new Nutrition Facts label for packaged foods.[8] Manufacturers must switch to the new label by either January 1, 2020, or January 1, 2021, depending on company size. Changes to the label include updated serving sizes, larger type size for servings and calories, updated daily values, and changes in the nutrients required to be disclosed on the label. In addition, added sugars must be disclosed on the label for the first time.

The USDA released its Final Rule on the National Bioengineered Food Disclosure Standard ("NBFDS") in December 2018, requiring food companies to revise product labeling to disclose the presence of bioengineered ingredients.[9] The NBFDS defines "bioengineered foods" as those that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature. The national labeling standard preempts state and local genetic engineering labeling requirements. Food companies should begin implementing the new labeling by January 1, 2020, and must be in compliance no later than January 1, 2022.

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7 A bill was recently introduced in the Senate that would permanently place the regulation of cell-based meat products under USDA's jurisdiction by amending the Federal Meat Inspection Act and the Poultry Products Inspection Act. Cell-Cultured Meat & Poultry Regulation Act of 2019, S. 1056, 116th Cong. (2019).

8 Food Labeling: Revision of the Nutrition and Supplement Facts Label, 81 Fed. Reg. 33741 (May 27, 2016).

9 National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65814 (Dec. 21, 2018).

FDA has asked stakeholders to provide comments on how plant-based milk, such as almond and soy milk, and other plant-based "dairy" products should be labeled.[10] FDA expressed support for the innovation of these alternative products while recognizing that some consumers may not realize that these products do not have the same nutritional value and/or attributes as cow milk. The dairy industry has urged FDA to enforce dairy labeling standards and stop alternative products from using the terms "milk," "cheese" and "yogurt," arguing that such titles are misleading. The National Milk Producers Federation submitted a citizen petition to FDA in February 2019, laying out this argument, and 10 members of the House of Representatives sent a letter to FDA agreeing with the dairy industry. On the other hand, the plant-based food industry has argued in favor of consumer choice and vowed to challenge the constitutionality of any action limiting the use of dairy terms. FDA's request for comments and statement indicates that change may be on the horizon. The effort is part of a larger multiyear Nutrition Innovation Strategy announced by FDA in March 2018.

Takeaway: The upcoming labeling changes will impact what consumers see on the package when shopping for food and could therefore impact profitability. Investors should assess how the new requirements will affect individual products.

Food Imports

The Food Safety Modernization Act ("FSMA") requires importers to perform certain activities to verify that imported food has been manufactured in accordance with applicable U.S. safety standards. Many companies were required to have a Foreign Supplier Verification Program ("FSVP") in place by May 30, 2017. Although FDA had refrained from enforcement to allow companies to come into compliance, the agency now appears to be actively enforcing the FSVP requirement. The lack of an FSVP was the most frequently cited observation during FDA inspections of U.S. food facilities in 2018, suggesting that FDA is regularly inspecting importers for compliance. And as of June 1, 2018, FDA had completed 256 inspections of foreign firms resulting in citations for good manufacturing practices ("GMP") violations, emphasizing the public health need for FSVPs.

In February 2019, FDA released its "Strategy for the Safety of Imported Food," outlining how the agency plans to improve its import oversight.[11] For example, FDA plans to work more closely with foreign regulatory authorities to share oversight responsibilities. By entering into formal arrangements with certain countries, FDA believes it will be

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[10] Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, 83 Fed. Reg. 49103 (Sep. 28, 2018).

[11] FDA Strategy for the Safety of Imported Food, https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm631747.htm (last updated Mar. 1, 2019).

able to redirect limited resources to higher-risk areas. FDA also plans to improve data analytics to maximize the effectiveness of border oversight.

Takeaway: If a food company is reliant upon importation, an investor should take a close look at the company's FSVP and foreign suppliers during the diligence process. FDA has extensive power at the border and can detain food products if they "appear" to be violative. FDA is expected to continue focusing on foreign imports and GMP issues, which could lead to supply chain disruptions.

Natural Claims

In November 2015, FDA asked the public for comments on the use of the term "natural" in food product labeling, including for genetically engineered foods or ingredients.[12] The agency had received considerable pressure, including through Citizen Petitions, to define and/or prohibit the use of the term. FDA's long-standing policy considers the term "natural" to mean that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food."[13] This definition suffers from serious flaws: for example, it does not address whether genetically modified foods would be considered natural, or whether the manufacturing process impacts whether a food is "natural." FDA has not taken further action since issuing the request for comments.

In the absence of FDA leadership on the subject, private litigation has proliferated. Companies are routinely challenged by private plaintiffs on the use of the term "natural" on their product labels. Because the meaning of the term is subject to varied interpretations, it is relatively easy for plaintiffs' lawyers, with enough creativity, to develop a theory that a particular food is "unnatural." Many courts have applied the primary jurisdiction doctrine and issued a stay in such cases, waiting for FDA to issue a final regulation defining the term "natural." The primary jurisdiction doctrine is applied in situations where a court defers to regulatory agency expertise. In a 2018 case, however, the judge considering a case against a snack bar company lifted a stay and allowed the lawsuit to proceed.[14] The court was uncomfortable waiting for FDA action that may not be forthcoming and stated that there is "no indication whether the FDA is earnestly working toward a uniform 'natural' standard, or whether it has shelved that effort. […] As such, this court explained that it 'cannot sit idly by on an illusory

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[12] Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69905 (Nov. 15, 2015).

[13] *See* FDA, "Natural" on Food Labeling, https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm456090.htm (last updated Oct. 22, 2018).

[14] *In re* KIND LLC "Healthy and All Natural" Litig., No. 15-2645 (S.D.N.Y., entered February 11, 2019).

assurance that something is likely to happen.'"[15] No decision has yet been issued in the case.

Takeaway: Plaintiffs' lawyers often target "natural" claims on food products. FDA's continued lack of action may encourage even more lawsuits challenging these claims in the future. Investors should weigh the risk of lawsuits against the commercial benefits of using unqualified "natural" claims.

Dietary Supplement Enforcement

In February 2019, FDA announced that it intends to modernize and reform its oversight of the dietary supplement industry.[16] The agency expressed concerns about numerous bad actors selling products with dangerous or illegal ingredients. FDA believes that as the industry has gotten bigger—what was once a $4 billion industry of about 4,000 products is now an industry of over $40 billion and more than 50,000 products—FDA's oversight policies have not evolved quickly enough.

To address this, FDA has created a Dietary Supplement Working Group to examine how to improve oversight of the industry. FDA intends to deploy a rapid-response tool to alert the public when there is a safety risk associated with a dietary supplement ingredient and to issue Warning Letters when companies claim their supplements will treat serious conditions without FDA approval.[17] FDA, of course, is already issuing such Warning Letters and uses its existing enforcement authority to regulate the industry. In addition, on April 16, 2019, FDA unveiled its new Dietary Supplement Ingredient Advisory List, a rapid-response tool meant to quickly alert the public when FDA identifies ingredients that do not appear to be lawfully marketed in dietary supplements.[18] Congress is expected to weigh in on these issues, potentially along with other related regulatory issues such as the use of hemp and/or CBD in dietary supplements and the finalization of "new dietary ingredient" guidance.

Takeaway: The growing dietary supplement industry is once again going to come within FDA's microscope and investors should expect increased regulation and enforcement against outlier companies the agency believes are non-compliant,

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15 *In re* KIND LLC "Healthy & All Nat." Litig., 287 F. Supp. 3d 457, 470-71 (S.D.N.Y. 2018).

16 Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's New Efforts to Strengthen Regulation of Dietary Supplements by Modernizing and Reforming FDA's Oversight (Feb. 11, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm.

17 FDA recently issued 12 Warning Letters to companies selling supplements promoted to treat Alzheimer's disease. *E.g.*, FDA Warning Letter to Blue Ridge Silver (Feb. 5, 2019), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm630568.htm.

18 FDA, Dietary Supplement Ingredient Advisory List, https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm636081.htm.

particularly when a product presents a safety risk or claims (without authorization) to treat a serious disease or condition.

Dietary Supplements Containing Caffeine

FDA released a guidance document addressing the use of caffeine in dietary supplements in April 2018.[19] The guidance was issued in final form, without prior public comment, based upon FDA's determination that there is a significant threat to public health associated with pure and highly-concentrated caffeine products.

In the guidance, FDA cautioned that dietary supplements containing highly concentrated caffeine in powdered or liquid form (often sold in bulk containers with hundreds of doses) may be adulterated regardless of labeling, warnings, serving sizes and measuring devices. It is FDA's position that these products "present a significant public health threat because of the high risk that they will be erroneously used at excessive, potentially dangerous doses."[20] For other dietary supplements containing caffeine, FDA provided guidance on how to formulate safer supplements and acknowledged that caffeine is a lawful ingredient for inclusion in dietary supplements. Notably, FDA did not set forth a maximum level of caffeine but instead indicated that dietary supplements should not provide "an excessive amount of caffeine."

Takeaway: When investing in companies that market dietary supplements containing high levels of caffeine, it is important to review compliance with FDA's new guidance document as well as perform a safety review of the products. Safety concerns could lead to significant product liability exposure.

Hemp/CBD in Food and Dietary Supplements

Congress passed the 2018 Farm Bill in December 2018, legislation that included provisions lifting the federal prohibition on hemp production.[21] Enactment of this legislation has significant implications for the legality of CBD, a popular hemp derivative.

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[19] FDA, *Guidance for Industry: Highly Concentrated Caffeine in Dietary Supplements* (Apr. 2018), https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM604319.pdf.

[20] FDA News Release: FDA Takes Step to Protect Consumers Against Dietary Supplements Containing Dangerously High Levels of Extremely Concentrated or Pure Caffeine (Apr. 13, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604485.htm.

[21] The 2018 Farm Bill's hemp provisions build on the framework set forth in the Agricultural Act of 2014 (the "2014 Farm Bill"), which allowed for limited legal cultivation of hemp. Under the 2014 Farm Bill, hemp could be cultivated for research purposes under state-approved pilot programs connected to universities or state agricultural departments. H.R. 2642, 113th Cong. (2014).

The federal Controlled Substances Act of 1970 ("CSA") had long prohibited the growing, production, and sale of hemp, which fell under the definition of marijuana. The 2018 Farm Bill's hemp-specific provisions amend the CSA so that hemp, as long as it contains less than 0.3 percent tetrahydrocannabinol ("THC")—the primary psychoactive chemical in marijuana—no longer comes within the federal definition of marijuana. CBD, as a hemp derivative, is also removed from the purview of the CSA.

Notwithstanding hemp's removal from the CSA, the legality of foods and dietary supplements containing CBD remains problematic at the federal level. Specifically, the 2018 Farm Bill did not change FDA's authority to regulate products under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), and FDA has taken the position that CBD is impermissible for use in food and dietary supplements based upon operation of the statutory "exclusionary clause."[22]

In addition, FDA has intermittently sent Warning Letters to entities that sell CBD products, including dietary supplements and topical cosmetic products, for making unproven drug claims about CBD's health-related properties.[23] In a statement after passage of the 2018 Farm Bill, FDA reiterated that it intends to "take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products that can put consumers at risk and are being marketed in violation of the FDA's authorities."[24] At the same time, FDA acknowledged the potential opportunities for foods and dietary supplements containing CBD and hinted that the agency is evaluating whether it would be appropriate to develop a regulatory framework for bringing these products to market. FDA will hold a public meeting on the topic at the end of May 2019, but believes a legislative solution may be quicker and more efficient than proceeding via notice-and-comment rulemaking.

The 2018 Farm Bill also does not preempt state law and states could choose to regulate hemp and hemp-derived CBD in a more restrictive manner. Many states have indicated that the sale of CBD foods, dietary supplements, and cosmetics violates state law. Other states permit the sale of such products and still other states appear to be undecided.

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22 FDA, FDA and Marijuana: Questions and Answers (June 25, 2018), https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm.

23 *See, e.g.*, FDA Warning Letter to Hemp Oil Care (Feb. 26, 2015), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm436069.htm; FDA Warning Letter to Natural Organic Solutions (Feb. 26, 2015), https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm436066.htm.

24 Statement from FDA Commissioner Scott Gottlieb, M.D., on Signing of the Agriculture Improvement Act and the Agency's Regulation of Products Containing Cannabis and Cannabis-Derived Compounds (Dec. 20, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm.

Although CBD is currently considered unlawful for use in food and dietary supplements from an FDA regulatory perspective, there are certain hemp-derived ingredients that can be lawfully included in food. On December 20, 2018, FDA completed its evaluation of three generally recognized as safe ("GRAS") notifications for hemp seed-derived food ingredients. The GRAS notifications were submitted by Fresh Hemp Foods, Ltd. The agency had no questions about Fresh Hemp Food's conclusion that the following ingredients are GRAS for their intended conditions of use: hulled hemp seed, hemp seed protein powder, and hemp seed oil. The GRAS conclusions can apply to ingredients from other companies if they are manufactured in a way that is consistent with the notifications and meet the listed specifications. CBD was considered to be a low-level contaminant—not an ingredient—in these applications.

Takeaway: At the present time, foods and dietary supplements containing CBD remain unlawful on a federal level and state law must be assessed on a case-by-case basis. Investors should monitor FDA developments, however, as the agency has acknowledged the potential opportunities for these products and has committed to exploring whether and how to bring them to market.

Mandatory Recall Authority

In November 2018, FDA issued a guidance document on its authority to require mandatory food recalls, intended for situations when a party chooses not to conduct a voluntary recall. FDA may order a mandatory recall if there is a reasonable probability that the food is adulterated or misbranded under the FFDCA and that the food could cause serious illnesses or death. Although mandatory recall authority is seldom necessary (as most companies conduct "voluntary" recalls when appropriate), FDA has already exercised this authority by requiring the recall of powdered kratom due to salmonella contamination in April 2018.

Takeaway: FDA can and will force companies to remove potentially dangerous products from the food supply. Investors should keep this mandatory authority in mind, as FDA ultimately has the final say in any dispute over the necessity of a recall.

Cosmetics

Cosmetics are subject to less onerous regulation than other FDA-regulated consumer product categories. Nonetheless, FDA frequently issues Warning Letters to cosmetic companies based upon dissemination of inappropriate claims or sale of adulterated products (*e.g.*, sale of cosmetics with microbial contamination). In addition to risks associated with routine enforcement, investors must be cognizant of potential

forthcoming legislative and regulatory changes that may impact the viability of potential investment opportunities.

Legislative Reform

The cosmetics provisions of the FFDCA have remained virtually unchanged since 1938, leading Congress to question whether the regulatory regime should be updated to enhance agency oversight. With the election of a new Congress, many believe this may prove to be an opportune time for enactment of cosmetic reform legislation.

Frank Pallone (D-NJ), now Chairman of the House Energy and Commerce Committee, has consistently pushed for increased FDA regulation of cosmetics. He has written letters to FDA and specific cosmetic companies when safety issues have arisen in the past. Moreover, in August 2017, FDA responded to Chairman Pallone, noting the low percentage of import inspections and the high percentage of adverse findings when cosmetic imports were sampled and tested.

A number of stakeholders have recently expressed support for cosmetic legislative reform, including the Personal Care Products Council (the industry association) and a number of large cosmetic companies. Many smaller companies, however, are not necessarily supporting reform initiatives, as they are concerned that increased regulatory oversight would raise compliance costs and undermine competitiveness.

In early 2018, the Senate Health Committee sent stakeholders a draft cosmetic reform bill. The bill included, among other things, provisions requiring FDA to establish GMPs for cosmetics "consistent with international standards." At present, there are no FDA GMP regulations for cosmetic manufacturers. GMPs would likely require a significant investment by cosmetic manufacturers to update policies and procedures to comply with strict federal standards—similar to the burden already placed on other consumer product categories such as OTC drugs and dietary supplements. The bill did require FDA to consider the size and scope of the business when establishing GMPs, however, so it is possible that smaller businesses would have reduced obligations or a longer period to comply.

The bill would also require cosmetic manufacturers to register with FDA on a biannual basis, similar to requirements already in place for food manufacturing facilities. As part of the registration process, manufacturers would need to submit an ingredient listing for each cosmetic product. Cosmetic manufacturers would also be required to submit serious adverse event reports to the agency within 15 days of receipt. FDA would have the authority to suspend a facility's registration if serious health concerns arise or if the facility is out of compliance with GMPs. FDA could also suspend a cosmetic ingredient listing if the ingredient could cause serious harm or death to humans.

The cosmetic bill never made it out of the Senate Health Committee in 2018, but there is now a similar new bill in the Senate and Chairman Pallone (along with John Shimkus (R-IL)) recently circulated a discussion draft in the House. FDA welcomes the effort, urging Congress to modernize what it views as an outdated regulatory framework and to provide the agency with additional resources. In March 2019, FDA indicated that a regulatory framework could include registration and listing of products and their ingredients, GMP regulations, mandatory reporting of adverse events, access to company records (including consumer complaints) during FDA's routine or for-cause inspections, mandatory recalls, disclosure of known cosmetic allergens on a product's label, and ingredient review.[25] One significant sticking point the legislation must overcome prior to passage is whether the federal law would preempt state law.

Takeaway: A cosmetic reform bill would be a major development for cosmetic companies, which have historically been subject to less FDA oversight than other product categories. Compliance costs may require the expenditure of significant resources and may lead to significant M&A activity and private equity investment as smaller companies may need additional resources and financial support to come into compliance.

FDA Cosmetic Safety Efforts

In March 2019, FDA issued a Safety Alert warning consumers that asbestos had been identified in multiple cosmetic products (typically containing talc). FDA emphasized the lack of oversight afforded to the agency under the FFDCA and announced new safety efforts. First, FDA will be requesting information from cosmetic companies regarding the procedures they use to ensure cosmetics are safe in the absence of mandatory GMPs. Second, FDA urged cosmetic companies to voluntarily register products and ingredients in FDA's Voluntary Cosmetic Registration Program ("VCRP"). Third, FDA called upon cosmetic companies to proactively report adverse events, even though it is not required by law. Fourth, FDA announced that it will identify unsafe cosmetic ingredients and notify consumers of the applicable risks.

Takeaway: FDA recently emphasized its concern about potentially unsafe cosmetic ingredients. Investors need to be aware that even though FDA does not preapprove cosmetics, the agency may nonetheless enforce against unsafe or adulterated cosmetics and may also use its power of publicity to denounce cosmetics the agency believes are unsafe.

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[25] Statement from FDA Commissioner Scott Gottlieb, M.D., and Susan Mayne, Ph.D., Director of the Center for Food Safety and Applied Nutrition, on Tests Confirming a 2017 Finding of Asbestos Contamination in Certain Cosmetic Products and New Steps that FDA Is Pursuing to Improve Cosmetics Safety (Mar. 5, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632736.htm.

CBD in Cosmetics

CBD is a popular ingredient in topical cosmetic products, such as lotions that are rubbed into the skin. Although FDA has stated that using CBD in foods and dietary supplements is unlawful, there is currently no similar FDA prohibition for cosmetics.

The 2018 Farm Bill does not preempt state law and states may choose to regulate hemp and hemp-derived CBD in a more restrictive manner than the federal government. Some state officials have issued statements confirming that they view all CBD products as unlawful because CBD is covered under the state definition of "marijuana." Others are reevaluating their positions, including through potential state legislative action, and still others have expressly indicated that such products are lawful.

Takeaway: Although FDA has not taken the position that CBD cosmetics are unlawful, the products may still be prohibited in many states under state law.

Microneedling and Cosmetic Claims

FDA released draft guidance on microneedling products in September 2017.[26] Microneedling products use needles, micro-protrusion tips, or pins of varying lengths to penetrate the skin when rolled or stamped across or into the skin's surface. These products may be used for skin exfoliation or to minimize the appearance of scars or wrinkles. The guidance document provides insight into FDA regulation of a broader range of cosmetics, however, by addressing the line between products regulated as cosmetics and medical devices.

According to the guidance document, if a product is claimed to impact the skin deeper than the stratum corneum, FDA is likely to consider such a claim a "structure/function" claim and not a cosmetic appearance claim.[27] A structure/function claim would lead the product to be regulated as a medical device by FDA. Therefore, if a product is claimed to penetrate into the living layers of skin, or any deeper than the stratum corneum, FDA would consider the product to be a medical device and not a cosmetic. In addition, FDA may consider a product a medical device if its mechanism of action results in penetration beyond the stratum corneum, regardless of whether the product claims to do so.

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[26] FDA, *Draft Guidance for Industry and FDA Staff: Microneedling Devices* (Sep. 15, 2017), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm575923.pdf.

[27] FDA defines the "stratum corneum" as the superficial or outer layer of the epidermis, consisting of several layers of flat, keratinized, non-viable, peeling cells, and notes that the stratum corneum is a dead cell layer of skin, as opposed to living layers of skin. *Id.* at 6. The living layers of skin are layers of live cells and surrounding tissues (*e.g.*, connective tissue) within the epidermis, dermis and subcutis, including hair follicles and glandular structures. *Id.*

Takeaway: Investors should pay particular attention to cosmetic claims when performing due diligence. If claims are too aggressive and cross the cosmetic/drug-device dividing line, they may lead FDA to pursue enforcement.

E-Cigarettes and Tobacco Products

Congress granted FDA jurisdiction over tobacco products in the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), signed into law on June 22, 2009. FDA regulates traditional cigarettes, e-cigarettes, cigars, chewing tobacco, and other tobacco-derived products under the Tobacco Control Act.

FDA announced an aggressive posture toward e-cigarettes in November 2018.[28] FDA is particularly concerned by the rate of e-cigarette use among young people and aims to combat this by reducing access to flavored products that appeal to children. After meeting with the leadership of several large e-cigarette manufacturers, such as Altria Group and JUUL Labs, FDA announced a plan to require that all flavored e-cigarettes (other than tobacco, mint, and menthol flavors) be sold in age-restricted locations. FDA would also require enhanced age-verification standards for online sales. A draft guidance document released in March 2019 described these proposed policies and also suggested that FDA may act to remove all flavored cigars from the market.[29] Further details will be available when the guidance document is finalized. The agency is trying to walk the line between discouraging e-cigarette use by children and making these products available to adults already addicted to cigarettes who may use them as a healthier alternative to traditional cigarettes.

In January 2019, FDA held a hearing to address the potential development of drug therapies to help children quit e-cigarettes and other tobacco products.[30] FDA has signaled that it would support the development of innovative therapies to address this issue.

Although FDA's recent focus has been on e-cigarettes, the agency has also proposed notable policy changes addressing traditional cigarettes. In July 2017, FDA announced a

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[28] Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm.

[29] FDA, *Draft Guidance for Industry: Modifications to Compliance Policy for Certain Deemed Tobacco Products* (Mar. 2019), https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM633281.pdf.

[30] Eliminating Youth Electronic Cigarette Use: The Role for Drug Therapies Public Hearing (Jan. 18, 2019), https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm620744.htm.

Comprehensive Plan for Tobacco and Nicotine Regulation.[31] FDA has indicated that it may take regulatory actions to limit nicotine levels and restrict the sale of tobacco products with flavors, including menthol. Although the implementation of such policies may have a significant effect on the tobacco industry, the rulemaking process could take years and it is unclear whether the agency will have a sufficient legal basis to proceed with any of these initiatives.

Takeaway: During his tenure at the agency, Commissioner Gottlieb focused on tobacco regulation and proposed ambitious policy goals that could significantly impact the tobacco and e-cigarette industries. His departure from the agency calls the long-term viability of some of these initiatives into question, and investors should therefore monitor developments to discern the agency's direction over the coming months.

OTC Drugs

FDA regulates most OTC drugs via the OTC Drug Review. The goal of the review process is to create OTC monographs for therapeutic drug categories (*e.g.*, sunscreens, acne drugs, skin protectants). OTC monographs provide "recipes" covering acceptable ingredients, indications, and labeling. A drug marketed consistent with these conditions may be sold without preapproval by FDA.

Change may be on the horizon for the OTC drug category. Congressional reform bills appear to have bipartisan support and could be enacted within the next two years.

Legislative Reform

The OTC Drug Review has been moving at a glacial pace and many monographs have yet to be finalized since the process started in 1972. In addition, updating monographs based upon evolving scientific developments requires a lengthy process involving notice-and-comment rulemaking. Stakeholders across the spectrum agree that reform is necessary. FDA has acknowledged that "the lengthy . . . rulemaking procedures for establishing OTC monographs are not well-suited to addressing safety concerns that arise before or after a monograph is finalized, keeping pace with evolving science, or ensuring the consistent safety and effectiveness of varying formulations."[32]

Congress has been contemplating OTC Drug Review legislative reform for a number of years, and momentum has built significantly over the last year. In September 2017, the

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[31] FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm.

[32] FDA Response to American Dental Association Citizen Petition, Docket No. FDA-2017-P-4736 (Dec. 21, 2018).

House of Representatives released a draft of a monograph reform bill that would create an OTC monograph user fee program, allow for more efficient reviews and create an exclusivity period for new products to encourage innovation. A similar bill was introduced in the Senate in January 2018.

On January 8, 2019, the House passed the Over-the-Counter Drug Safety, Innovation and Reform Act, packaged with the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019. The bill passed by an overwhelming majority and now awaits Senate action. The Senate has added the bill to its calendar. If passed, the legislation would increase the potential for innovation: new monographs would be finalized faster and no longer stalled in a decades-long review process, and certain OTC drug products would be eligible for limited market exclusivity (up to 18 months).

Takeaway: In conducting diligence, sponsors looking to acquire OTC drug companies or products should be aware of the status of the monograph for the particular product and carefully evaluate the potential for future change that could affect the product's marketing status. Potential exclusivity periods for new OTC products, as proposed in draft legislation, may provide sponsors with good investing opportunities in innovative OTC drug companies.

Expanding OTC Access to Prescription Drugs

In what would be a significant deregulatory move, FDA is planning to propose regulations that would increase access to prescription drugs by allowing them to be sold over the counter with added safeguards. FDA intends to promote innovative approaches to ensure that customers can self-select appropriate drugs on their own. FDA stated, for example, that the new rule could include the "use of self-selection questions on a mobile medical app prior to permitting access to the drug, or other innovative technologies to improve safety."[33] In this way, FDA could increase the number of drugs made available to consumers over-the-counter via the "OTC Switch" process.

Takeaway: Allowing additional prescription drugs to be sold over the counter could provide unique opportunities for sponsors who follow the development of these regulations.

Sunscreens

FDA released a guidance document addressing the marketing status of OTC sunscreens in May 2018.[34] The guidance document addressed a wide range of issues, including

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[33] Scott Gottlieb, M.D., *Looking Ahead: Some of FDA's Major Policy Goals for 2018*, FDA Voice (Dec. 14, 2017), https://blogs.fda.gov/fdavoice/index.php/2017/12/looking-ahead-some-of-fdas-major-policy-goals-for-2018/.

[34] FDA, *Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without an Approved Application* (May 2018),

permissible ingredients, "broad spectrum" claims, SPF testing, warnings and the use of sunscreen ingredients in insect repellants. A notable aspect of the guidance document, however, related to dosage forms. Specifically, according to the guidance document, FDA has concluded that the following sunscreen dosage forms are permissible: sprays (provided the products are appropriately labeled in accordance with the guidance document), oils, lotions, creams, gels, butters, pastes, and ointments. In contrast, the following dosage forms are tentatively *impermissible*: wipes, towelettes, powders,[35] body washes, and shampoos.

FDA subsequently issued a proposed rule addressing sunscreen regulation in February 2019. Until a final rule is issued (by November 26, 2019) the agency generally will follow the policy outlined in the aforementioned guidance document. In the proposed rule, however, FDA signaled that sunscreen wipes, towelettes, body washes, shampoos, and other novel dosage forms would be prohibited. FDA expects to allow sprays, oils, lotions, creams, gels, butters, pastes, ointments and sticks. FDA also signaled that two sunscreen ingredients currently identified in the monograph, PABA and trolamine salicylate, would no longer be allowed in sunscreens and that 12 other sunscreen ingredients may also ultimately need to be removed from the market.

Takeaway: When investing in companies that sell sunscreens, it is important to review compliance with FDA's new guidance document and proposed rule, paying particular attention to sunscreen ingredients and dosage forms.

Wearables and Mobile Medical Apps

In June 2017, FDA introduced the "Digital Health Innovation Action Plan," outlining FDA's efforts to foster digital health innovation. In his announcement, Commissioner Gottlieb stated that FDA can "help reduce the development costs for [digital health] innovations by making sure that [FDA's] own policies and tools are modern and efficient, giving entrepreneurs more opportunities to develop products that can benefit

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM259001.pdf. The guidance document only applies during the interim period until FDA issues a final over-the-counter drug sunscreen monograph. In addition, the guidance document does not address the small percentage of sunscreens marketed pursuant to marketing applications such as new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs").

[35] In response to a Citizen Petition filed by Bare Escentuals Beauty, FDA concluded that the sunscreen powder dosage form is eligible for inclusion in the OTC Drug Review but that additional safety and efficacy data are required in order for powdered sunscreens to be included in the final monograph. FDA Response to Bare Escentuals Beauty, Inc. Citizen Petition, Docket No. FDA-1978-N-0018-0741 (Feb. 21, 2019). It is therefore lawful to market sunscreen powders at the moment, but it is possible that FDA could order them off the market after it completes its review.

people's lives."[36] As part of the plan, which implements Congress's goals in the 21st Century Cures Act, FDA is in the process of issuing new draft and final guidance documents related to medical software and digital health products.

We expect FDA to continue focusing its regulatory efforts on high-risk products, while loosening the regulatory burdens on lower-risk digital health products, consistent with the mandates of the 21st Century Cures Act. Investors may be able to identify product categories, such as general wellness, where products can be brought to market quickly without FDA pre-approval.

Software Pre-certification ("Pre-Cert") Pilot Program

FDA introduced the Pre-Cert Pilot Program in 2017. Through this program, FDA intends to place the regulatory emphasis on the developer of the technology rather than the product itself. In the pilot program, FDA is reviewing a number of companies' quality systems for software design, validation, and maintenance, to potentially pre-certify the companies and allow for a lower bar for any new digital health products distributed by those companies—perhaps by allowing them to submit less information or even forgo premarket review altogether.

In January 2019, FDA announced it was entering the pilot program test phase and issued updated documents describing the pilot program. In the test phase, FDA intends to confirm that the Pre-Cert program provides reasonable assurance of safety and effectiveness for software products. If the program is successful, FDA may expand it to other product categories in the future, but it will likely need to overcome congressional scrutiny. In October 2018, Democratic Senators Elizabeth Warren (MA), Patty Murray (WA) and Tina Smith (MN) sent a letter to FDA expressing a number of concerns with the program, including whether the agency has the statutory authority to establish it.

Takeaway: FDA recognizes its role in shepherding digital health products to market and aims to reduce hurdles to product approval through the Pre-Cert program. The agency is working to foster innovation, particularly in areas with frequent iteration and product updates. Traditional regulatory frameworks must be adjusted, however, and sponsors should be aware that it may take creativity and persistence to work through the regulatory requirements.

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[36] Scott Gottlieb, M.D., "Fostering Medical Innovation: A Plan for Digital Health Devices," *FDA Voice* (June 15, 2017), https://blogs.fda.gov/fdavoice/index.php/2017/06/fostering-medical-innovation-a-plan-for-digitalhealth-devices/.

Health-Related Software Not Requiring FDA Approval or Clearance

FDA issued draft guidance documents addressing whether a software program or mobile medical app will require preapproval or clearance as a medical device. One such guidance document explains how FDA will implement a section of the 21st Century Cures Act that places certain software functions outside of the medical device definition and thus significantly lowers the regulatory burden for the commercial distribution of these software products.[37] For example, software meant for administrative support, electronic patient records, and to help maintain or encourage a healthy lifestyle will not be regulated as medical devices.[38] These areas may be particularly attractive for new development.

FDA has also attempted to clarify the type of clinical decision support ("CDS") software that will be subject to oversight and/or enforcement. In draft guidance, FDA stated that patient decision support software, such as programs designed to remind patients to take medication on time, will not be subject to FDA regulation.[39] In addition, software that allows physicians to independently review the program's clinical recommendations may also not be regulated as a device, but FDA will continue to enforce oversight of software programs that are intended to process or analyze medical information. Critics claim that the guidance is overly ambiguous and does not recognize that physicians may not be able to review recommendations in some instances—such as when a program uses a complicated algorithm—but that these programs may nonetheless be sufficiently low risk to make FDA oversight unnecessary.

Takeaway: Certain categories of health-related mobile apps and software programs may go to market without FDA approval or clearance. Investors should tread carefully because there are significant regulatory ambiguities and each product should be subject to regulatory analysis before bringing it to market.

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[37] FDA, *Draft Guidance for Industry and Food and Drug Administration Staff: Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act* (Dec. 8, 2017), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf.

[38] According to the guidance document, "software with healthy lifestyle claims, such as weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function, are not devices when not related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition." *Id.* at 8. FDA provides the following examples of products that would not be devices: (1) "A mobile application that plays music to soothe and relax an individual and to manage stress;" (2) "A mobile application that solely monitors and records daily energy expenditure and cardiovascular workout activities to allow awareness of one's exercise activities to improve or maintain good cardiovascular health;" and (3) "A mobile application that monitors and records food consumption to manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity." *Id.* at 9.

[39] FDA, *Draft Guidance for Industry and Food and Drug Administration Staff: Clinical and Patient Decision Support Software* (Dec. 8, 2017), https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm587819.pdf.

Medical Device Cybersecurity

Virtually all software and networked products, including digital health products, are susceptible to cybersecurity vulnerabilities. Because of the heightened risk in recent years, FDA has become increasingly focused on the issue and has taken significant steps to develop policies and guidance to assist manufacturers in addressing cybersecurity-related regulatory issues.[40]

Similarly, Congress has held oversight hearings designed to identify emerging risks and continues to consider legislative solutions, while media and grassroots organizations have expressed concerns about emerging cybersecurity vulnerabilities (particularly in light of recent cybersecurity-related Safety Communications issued by FDA and high-profile breaches in the healthcare industry).

Debevoise & Plimpton LLP partnered with the Medical Device Innovation Consortium (MDIC), the first non-profit public-private partnership with the sole objective of advancing medical device regulatory science, to prepare the recently-released "Medical Device Cybersecurity Report: Advancing Coordinated Vulnerability Disclosure."[41] This report provides in-depth information about the legal and regulatory issues associated with medical device cybersecurity, as well as best practices for managing risk.

Takeaway: Investors in OTC medical devices, mobile medical apps, and software products should pay attention to cybersecurity issues during the diligence process, as FDA is expected to place an increasing emphasis on medical device cybersecurity in the future.

Conclusion

Private equity sponsors investing in consumer products should be encouraged by the direction FDA is currently taking. Legislative reform efforts and new FDA policies and initiatives create exciting investment opportunities by encouraging innovation, reducing regulatory burdens, and benefitting companies well positioned to respond to a changing regulatory environment. Successful sponsors will be those who keep abreast

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[40] FDA, *Draft Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* (Oct. 18, 2018), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocument/UCM623529.pdf; FDA, *Guidance for Industry and FDA Staff: Postmarket Management of Cybersecurity in Medical Devices* (Dec. 28, 2016), https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm482022.pdf.

[41] Report available at https://www.debevoise.com/news/2018/10/debevoise-collaborates-with-industry.

of the changes and who can be nimble and creative as policies evolve. Understanding the nuanced ramifications of the many new FDA and Congressional initiatives on the consumer product industry is critical to making thoughtful and forward-looking investments.

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Please do not hesitate to contact us with any questions.

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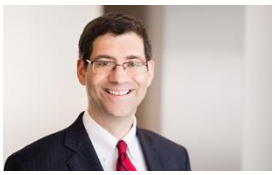

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