

# **Significant Regulatory, Policy, and Enforcement Developments: 2020**

## **A Tale of the Three C's: COVID-19, Cannabis, and CBD**

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To state the very obvious, the COVID-19 pandemic has had and will continue to have a profound impact on the U.S. Food and Drug Administration (FDA or agency). However, there were significant regulatory, policy, and enforcement developments in 2020 not having anything to do with the global pandemic, including in the cannabis and cannabidiol (CBD) spaces.

### **COVID-19**

The agency published its first statement regarding the novel coronavirus on January 27, 2020, in an attempt to assure the public that FDA was acting quickly “to facilitate the development and availability of investigational medical products to help address this urgent public health situation.”<sup>1</sup> Shortly thereafter, on January 31, 2020, then-Department of Health and Human Services (HHS) Secretary Alex M. Azar II declared a public health emergency pursuant to his authority under Section 319 of the Public Health Service Act.<sup>2</sup> Over one year later, after industry’s unprecedented push for expanded testing, rapid manufacturing and sourcing of personal protective equipment (PPE), development of investigational therapies, and studying and securing authorization for multiple vaccine candidates, there is light at the end of the tunnel.

In spite of the fairly successful vaccine rollout to date, FDA’s portfolio will continue to be dominated by COVID-19 throughout 2021. Since former Secretary Azar declared the public health emergency over a year ago, the agency has relied on its authority under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which permits the FDA Commissioner to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to

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<sup>1</sup> Press Release, U.S. Food & Drug Admin., FDA Announces Key Actions to Advance Development of Novel Coronavirus Medical Countermeasures (Jan. 27, 2020), <https://www.fda.gov/news-events/press-announcements/fda-announces-key-actions-advance-development-novel-coronavirus-medical-countermeasures>.

<sup>2</sup> Press Release, U.S. Dep’t of Health & Human Servs., Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus (Jan. 31, 2020), <https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html>.

diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when there are no adequate, approved, and available alternatives that exist.<sup>3</sup> Under this Emergency Use Authorization (EUA) provision, FDA has permitted the marketing of hundreds of products that have not been subject to ordinary (*i.e.*, non-emergency) premarket review, including face masks, surgical masks, and respirators, as well as PPE and PPE decontaminants, diagnostic and serological (*i.e.*, antibody) tests, ventilators, patient monitoring devices, and, as of April 9, 2021, three safe and effective COVID-19 vaccines.<sup>4</sup> These products must all satisfy certain criteria in order to receive an EUA, and each authorization letter specifies, in some form, that the “EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of [the product] during the COVID-19 outbreak is terminated.”<sup>5</sup>

While, unfortunately, the public health emergency will not be lifted any time soon, we anticipate that manufacturers of items marketed pursuant to EUA will eventually face the same dilemma: Whether to spend the necessary resources to register their establishments and pay the required registration fee, as well as apply for, and obtain, the requisite premarket clearance or approval required to market their product(s) in non-emergency settings. These expenses will prove difficult for certain firms that were not previously subject to FDA’s jurisdiction but who pivoted their manufacturing operations to assist the public during the early months of the pandemic (*e.g.*, alcohol producers pivoting to making hand sanitizer, although HHS recently clarified that FDA’s newly enacted over-the-counter (OTC) monograph drug facility fees will not apply to those companies that first entered the OTC drug market only to produce hand sanitizer during the COVID-19 public health emergency).<sup>6</sup> Beyond the burdens on industry not used to FDA compliance and related costs, the agency will also be burdened by a return to non-emergency review of products (*e.g.*, handling an influx of premarket applications).

## CANNABIS

Despite COVID-19, 2020 was marked by significant cannabis sector growth, due in large part to the impact of cannabis ballot initiatives in the November 2020 elections. Given the strength of public support for cannabis legalization (currently, sixty-eight percent of Americans support legalization), it is not surprising that state cannabis policy momentum in the U.S. continued to grow last year, a trend which shows no signs of slowing down.<sup>7</sup> On November 4, 2020, voters in five states approved

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<sup>3</sup> 21 U.S.C. § 360bbb-3.

<sup>4</sup> See U.S. Food & Drug Admin., Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization (reissued Feb. 25, 2021), <https://www.fda.gov/media/144412/download>; U.S. Food & Drug Admin., Moderna COVID-19 Vaccine EUA Letter of Authorization (reissued Feb. 25, 2021), <https://www.fda.gov/media/144636/download>; U.S. Food & Drug Admin., Janssen COVID-19 Vaccine EUA Letter of Authorization (Feb. 27, 2021), <https://www.fda.gov/media/146303/download>.

<sup>5</sup> See *id.*

<sup>6</sup> *FDA In Brief: FDA Republishing Fee Rates under the Over-the-Counter Monograph Drug User Fee Program*, U.S. FOOD & DRUG ADMIN. (Mar. 25, 2021), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-republishing-fee-rates-under-over-counter-monograph-drug-user-fee-program>.

<sup>7</sup> Megan Brenan, *Support for Legal Marijuana Inches Up to New High of 68%*, GALLUP (Nov. 9, 2020), <https://news.gallup.com/poll/323582/support-legal-marijuana-inches-new-high.aspx>.

ballot measures to authorize medical and/or adult use cannabis programs.<sup>8</sup> At present, thirty-seven states and the District of Columbia have medical programs, or have paved the way for the same, with seventeen of those states also having adult-use (*i.e.*, recreational) programs.<sup>9</sup>

Mississippi and South Dakota approved measures to regulate medical cannabis, and Arizona, Montana, New Jersey, and South Dakota approved measures to regulate adult-use cannabis.<sup>10</sup> South Dakota became the first state to authorize medical and adult-use cannabis simultaneously.<sup>11</sup> The timelines in other states, such as Mississippi and South Dakota, are less clear, with program launches likely in 2022.<sup>12</sup>

These state developments make one thing clear: Support for cannabis does not conform with geographic or traditional political lines. Anyone who assumes that only coastal blue states will support cannabis does so at their own peril. Voters in Mississippi, Montana, and South Dakota delivered solid victories for former President Trump, but these same voters approved cannabis ballot initiatives by even wider margins.<sup>13</sup> Federal cannabis reform largely stalled in 2020, but given Democratic control of the House of Representatives, the Senate, and the White House, that could change moving forward. In December 2020, the U.S. House of Representatives passed (228-164, mostly, but not entirely, along party lines) the Marijuana Opportunity Reinvestment and Expungement Act (MORE Act) that, if enacted, would end the federal prohibition and criminalization of marijuana by descheduling it from the Federal Controlled Substances Act.<sup>14</sup> Such legislation was not taken up by the Senate, but marked the first time that Congress has ever voted on the issue. In light of the January 6, 2021 Georgia runoff elections (Sens. Raphael Warnock's and Jon Ossoff's wins have split the Senate 50-50, with Vice President Kamala Harris serving as the tiebreaker), cannabis reform legislation may receive a warmer reception under the Biden Administration.<sup>15</sup> The prospect of Senate approval of the MORE Act is not clear, given that Democrats could very well retain the chamber's filibuster rule, meaning that sixty votes could be required to invoke cloture (*i.e.*, end the filibustering of a bill). Approval of more modest approaches, like that in the Strengthening the Tenth Amendment Through Entrusting States (STATES) Act and/or the Secure And Fair Enforcement (SAFE) Banking Act could be more likely.<sup>16</sup> However, in an

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<sup>8</sup> *State Medical Marijuana Laws*, NAT'L CONF. OF STATE LEGS. (last updated Apr. 5, 2021), <https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx>.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Mississippi Medical Marijuana Program*, MISS. STATE DEP'T OF HEALTH (last accessed Apr. 18, 2021), [https://msdh.ms.gov/msdhsite/\\_static/30,0,425.html](https://msdh.ms.gov/msdhsite/_static/30,0,425.html); S.D. Constitutional Amendment (Marijuana Legalization Initiative), [https://sdsos.gov/elections-voting/assets/2020\\_CA\\_LegalizeMarijuana\\_AG\\_Statement.pdf](https://sdsos.gov/elections-voting/assets/2020_CA_LegalizeMarijuana_AG_Statement.pdf); S.D. Measure 26 (Medical Marijuana Initiative), <https://sdsos.gov/elections-voting/assets/MedMarijPetitionApproved.pdf>.

<sup>13</sup> Alice Park, Charlie Smart, Rumsey Taylor & Miles Watkins, *An Extremely Detailed Map of the 2020 Election*, N.Y. TIMES (last accessed Apr. 18, 2021), <https://www.nytimes.com/interactive/2021/upshot/2020-election-map.html>.

<sup>14</sup> H.R. 3884, 116th Cong. (2019–2020).

<sup>15</sup> *Georgia U.S. Senate Runoff Results*, THE WASHINGTON POST (Jan. 19, 2021), <https://www.washingtonpost.com/elections/election-results/georgia-senate-runoffs-2021/>.

<sup>16</sup> See H.R. 2093, 116th Cong. (2019–2020); H.R. 1595, 116th Cong. (2019–2020).

interview in early April, Senate Majority Leader Chuck Schumer (D-N.Y.)—who is drafting new federal marijuana reform legislation with Sens. Cory Booker (D-N.J.) and Ron Wyden (D-Ore.)—indicated that the U.S. Senate will act on marijuana legalization with or without President Biden’s support.<sup>17</sup>

## CBD

Similarly, 2021 could see further progress related to FDA’s regulation of hemp-derived cannabidiol (CBD) in consumer products, but it may be too soon to tell.

On July 22, 2020, FDA sent to the White House Office of Management and Budget (OMB) for review a draft guidance, “Cannabidiol Enforcement Policy.”<sup>18</sup> As the document was still pending review when former President Trump left office, it was subject to a regulatory “freeze” instituted by President Biden. Just a day after President Biden was inaugurated, on January 21, 2020, FDA withdrew the enforcement policy; it is not yet clear if/when the agency will release the policy (and whether it needs to go back to OMB or if FDA could issue it unilaterally), although some have predicted it could be released at any time.<sup>19</sup> Despite many predictions about what the document might contain—including by the authors—it appears that no one outside of the agency or OMB has yet seen the guidance.<sup>20</sup>

Also on July 22<sup>nd</sup>, FDA announced the availability of a draft guidance for industry, “Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research,” which may provide some insight into how the agency will regulate CBD products in the future.<sup>21</sup> On November 19, 2020, FDA held a public hearing regarding sex and gender differences in CBD use and responses, which made clear that, although the agency has made some progress in its research and assessment of CBD products across user groups, the agency still has many unanswered questions about the science, safety, and quality of products containing CBD.<sup>22</sup>

On the enforcement side, on December 17, 2020, the Federal Trade Commission (FTC) took action against six sellers of CBD-containing products for allegedly making a wide range of scientifically unsupported claims about their ability to treat serious

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<sup>17</sup> Natalie Fertig, *Schumer: Senate Will Act on Marijuana Legalization With or Without Biden*, POLITICO (Apr. 3, 2021), <https://www.politico.com/news/2021/04/03/schumer-senate-marijuana-legalization-478963>.

<sup>18</sup> See Office of Info. & Reg. Affs., Office of Mgmt. & Budget, *Cannabidiol Enforcement Policy; Draft Guidance for Industry; Availability* (received July 22, 2020; concluded date Jan. 21, 2021), <https://www.reginfo.gov/public/do/eoDetails?rrid=130911>.

<sup>19</sup> *Id.*

<sup>20</sup> 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/>.

<sup>21</sup> CANNABIS AND CANNABIS-DERIVED COMPOUNDS: QUALITY CONSIDERATIONS FOR CLINICAL RESEARCH GUIDANCE FOR INDUSTRY, DRAFT GUIDANCE FOR INDUSTRY, U.S. FOOD & DRUG ADMIN. (July 2020), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cannabis-and-cannabis-derived-compounds-quality-considerations-clinical-research-guidance-industry>.

<sup>22</sup> *Scientific Conference: CBD and Other Cannabinoids: Sex and Gender Differences in Use and Responses*, U.S. FOOD & DRUG ADMIN. (Nov. 19, 2020), <https://www.fda.gov/science-research/womens-health-research/scientific-conference-cbd-and-other-cannabinoids-sex-and-gender-differences-use-and-responses>.

health conditions.<sup>23</sup> FDA took similar action on December 22, 2020, issuing five Warning Letters to companies for making similar impermissible, aggressive health claims.<sup>24</sup> These enforcement measures largely mirror FTC and FDA’s prior concerns with unlawfully marketed CBD products that pose the greatest risk of harm to the public.

Although President Biden has yet to name his pick for FDA Commissioner as this book goes to press—something with which several former commissioners have taken issue—Janet Woodcock, M.D., an agency veteran who most recently served as the Director of FDA’s Center for Drug Evaluation and Research (CDER) is currently serving as Acting Commissioner.<sup>25</sup> If she is nominated by President Biden to serve as Commissioner of the agency, which some have predicted, we expect—given her background and portfolio at the agency related to drug products—that FDA’s protracted review of CBD could continue. One has to wonder, though: If federal and state cannabis reform efforts continue, will FDA’s approach to CBD remain the same? With that said, the agency’s position on CBD has nothing to do with its derivation from hemp, a cannabis varietal, and everything to do with CBD being studied and approved as a drug before it was marketed as an ingredient in foods.

As industry and Congress grow increasingly impatient with FDA related to the agency’s relative inaction on CBD, we expect a renewed legislative push in 2021 for hemp-derived CBD to be permitted as a dietary ingredient for use in supplements. H.R. 8179 was the legislative vehicle in the 116th Congress; it will need to be reintroduced in the 117th Congress.<sup>26</sup> While Reps. Kurt Schrader (D-Ore.) and Morgan Griffith (R-Va.) will likely reintroduce their legislation early this year, some in Congress might wait to see if FDA’s enforcement policy addresses the legislation’s goals (spoiler alert: it will not, at least not nearly to the same degree as the legislation would). Regarding the bill, it will be interesting to see how much Congress listens to FDA’s “technical comments” related to the same.<sup>27</sup> The agency’s recent comments on the bill differ greatly from the approach some members of Congress are pursuing.

At any rate, CBD and cannabis remain topics of great interest to stakeholders and the public, and we expect to see more federal and state legislative and regulatory action in 2021.

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<sup>23</sup> Press Release, Fed. Trade Comm’n, FTC Announces Crackdown on Deceptively Marketed CBD Products (Dec. 17, 2020), <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-announces-crackdown-deceptively-marketed-cbd-products>.

<sup>24</sup> Press Release, U.S. Food & Drug Admin., FDA Warns Companies Illegally Selling CBD Products (Dec. 22, 2020), <https://www.fda.gov/news-events/press-announcements/fda-warns-companies-illegally-selling-cbd-products>.

<sup>25</sup> Beth Snyder Bulik, *Former FDA Chiefs Pressure Biden to Nominate a New Commissioner—And Quickly*, FIERCE PHARMA (Mar. 11, 2021), <https://www.fiercepharma.com/marketing/former-fda-chiefs-pressure-biden-to-nominate-a-new-commissioner>.

<sup>26</sup> H.R. 8179, 116th Cong. (2019–2020).

<sup>27</sup> Josh Long, *FDA, Congress Differ on How CBD Should be Regulated in Supplements*, NATURAL PRODUCTS INSIDER (Nov. 24, 2020), <https://www.naturalproductsinsider.com/regulatory/fda-congress-differ-how-cbd-should-be-regulated-supplements>.