

The 2018 Farm Bill Brings Significant Changes to the Cannabis Industry While the FDA Retains a Central Role

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Lately cannabidiol (or CBD), a nonintoxicating component of the marijuana plant, appears to be everywhere. It can be found – online and in brick-and-mortar stores alike – as a touted ingredient to foods, drinks, dietary supplements and cosmetics, among other consumer products. A consumer might assume that the newfound prevalence of these products stems from a watershed moment completely upending cannabis law. But there hasn't been such a moment, at least not yet.

Many in the cannabis industry had hoped that the passage of the 2018 Farm Bill would be a game-changer in federal regulation. In many respects, the legislation lived up to the hype. Significantly, the Farm Bill carved out a distinction between two forms of cannabis: marijuana and hemp. Marijuana, which is listed as a Schedule 1 controlled substance under the Controlled Substances Act, can cause intoxicating effects owing to relatively high levels of its psychoactive component – tetrahydrocannabinol or (THC). Hemp, by contrast, is defined by the Farm Bill as cannabis having less than 0.3 percent THC content, even though it still retains other biologically active components, or cannabinoids, including CBD. From a regulatory perspective, the upshot of the distinction between marijuana and hemp is that a consumer of hemp-derived products, such as CBD, cannot get "high," irrespective of the amount consumed.

The Farm Bill removed hemp and hemp-derived products from the list of Schedule 1 controlled substances, and set out a regulatory roadmap for the hemp industry. The legislation instructs states to develop their own regulatory plans to govern the cultivation, licensing, testing and commercial sale of such products within their jurisdictions. These plans are to be submitted to the US Department of Agriculture. The Secretary of Agriculture is to release a stopgap federal plan to apply to states that opt not to promulgate their own regulations. While states retain the right to regulate the hemp industry in a stricter manner than the federal regime, they are prohibited from barring the interstate transportation of these products through their borders.

For all these changes, though, the Farm Bill left certain key regulatory structures undisturbed. Most notably, the US Food and Drug Administration retained jurisdiction to regulate hemp and hemp-derived products pursuant to the Food, Drug and Cosmetics Act. Perhaps anticipating early movers in the industry once the Farm Bill was enacted, the FDA released a position statement just after the bill was signed into law. In it, FDA Commissioner Scott Gottlieb wrote that the FDA continues "to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds." The statement re-urged the FDA's position that "it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived." The statement advised that the FDA would be holding hearings to evaluate how it will

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treat hemp and hemp-derived products going forward.

The only certainty here is more change to come in the near future. The states will promulgate their regulations for the hemp industry. The Department of Agriculture will articulate its plan for states that do not develop one of their own. The FDA will eventually release its new position on hemp derivatives. Meanwhile, individual cities may take their own enforcement actions. Through it all, market participants large and small will be working to understand this regulatory patchwork and how to comply with it. In sum, those interested in starting or expanding their hemp business can expect further shifts in the dynamic legal landscape.