As predicted by our colleagues earlier this month, outgoing Commissioner Scott Gottlieb of the U.S. Food and Drug Administration (FDA) released a comprehensive press release setting forth actions for possible FDA regulation of CBD products. FDA’s actions to create a regulatory framework include:

- A public hearing scheduled for May 31, 2019 for stakeholders – both proponents and opponents – to share CBD challenges and experiences, including public safety opinions. Given the interest in CBD and the passage of the 2018 Farm Bill, which encourages the development of hemp products, the hearing will cover such topics as: (1) health and safety; (2) manufacturing and product quality; and (3) marketing, labeling, and sales of CBD products.

- The creation of an internal working group to “explore potential pathways for dietary supplements and/or conventional foods containing CBD to be lawfully
A revamped FAQ on FDA’s website with new answers and guidance regarding CBD and THC products.

While the press release advances new steps to a regulatory framework for CBD products, FDA also reinforced its position that introducing CBD or THC infused products into interstate commerce, including marketing CBD and THC dietary supplements, continues to be illegal. In furtherance of this position, FDA released three warning letters to businesses marketing CBD products for using “egregious and unfounded claims aimed at vulnerable populations.” Chief among FDA’s concerns are:

- The widespread availability of CBD products and the considerable unanswered questions and potential health risks associated with the consumption of CBD products;
- The risk of liver disease and injury associated with collective exposure to CBD;
- That research will be negatively impacted by allowing universal availability to CBD products – research that would otherwise FDA’s drug review process and potentially support approval; and
- That widespread availability to CBD products will encourage patients to replace evidence-based or appropriate medical treatment with CBD products, which are not currently approved for medical treatment.

Warning Letters

FDA has a long history of enforcement actions against not only companies touting CBD and THC benefits but also companies that misbrand drugs and/or promote non-approved drugs generally. While FDA’s past warning letters have warned against exaggerated claims about CBD's ability to treat or cure certain diseases such as cancer, autoimmune disease, and opioid dependence, FDA's recent warning letters included some new concerns. For example, FDA warned businesses that it is illegal to label a product containing CBD so that the label suggests the contents are food. In addition, for the first time, the warning letters include a statement from the FTC that any deceptive advertisements of CBD products could be a violation of the FTC Act. These new warnings are a clear indication of FDA’s intent to crack down on what it considers to be deceptive advertising.

While FDA may be moving towards regulating CBD companies, it is clear that FDA will continue to hold companies accountable for making unsubstantiated claims about CBD, cannabis, and cannabis-derived products.

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