July 18, 2019

ATTORNEY GENERAL RAOUL URGES FDA TO PARTNER WITH STATES TO PROTECT CONSUMERS OF CANNABIS-DERIVED PRODUCTS

Raoul & 35 Attorneys General Support Continued Study of CBD and Other Cannabis Products; Call on Federal Government to Include AGs in Oversight of Emerging Market

Chicago — Attorney General Kwame Raoul, along with a coalition of 35 attorneys general, urged federal cooperation with the states to protect consumers from false advertising and harms to their health from products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD).

In a comment letter filed with the Food and Drug Administration (FDA), Raoul and the coalition highlight the need for research into the risks and potential benefits of cannabinoid products to inform consumers and assist in state-level regulation. They also encourage the FDA to continue partnering with state consumer protection authorities as it considers guidelines for this emerging market.

"As Attorney General, it is my responsibility to protect Illinois consumers by enforcing our consumer protection laws," Raoul said. "I urge the FDA to include state attorneys general in oversight over the emerging market of cannabis-derived products so we can continue to protect consumers and ensure they are not at risk of misleading advertising or exposed to products that could be harmful to their health."

The Farm Bill, passed in December 2018, removed cannabis products containing less than .3 percent of THC, the main psychoactive compound in cannabis, from the Schedule I list of drugs prohibited under the Controlled Substances Act. As a result, companies across the country have started to manufacture and sell varieties of cannabis commonly classified as "hemp." Hemp contains little THC but large amounts of CBD, a compound that has been touted by some to treat a wide variety of health concerns.

The Farm Bill permits states to come up with their own "Comprehensive Regulatory Plans" to regulate the CBD industry within their borders. Those plans will be reviewed by the federal government for approval. In the interim, the CBD industry has expanded in the last six months, and businesses are operating throughout the country without much oversight.

In the public comments to the FDA, Raoul and the coalition call for:

- **State and federal cooperation around cannabis-derived products:** As the primary enforcers of state laws and consumer protections, state attorneys general want to ensure the safety of CBD and other cannabis-derived products that are reaching consumers. They are also concerned that companies may rely on misleading advertising and unsubstantiated claims to lure consumers to use their products. The letter urges the FDA to include state attorneys general in the process as the agency considers regulatory oversight in testing and manufacturing of these products.
- **Continued study of the potential risks and benefits of these products:** To keep consumers safe and help them make informed decisions, Raoul and the coalition encourage the FDA to study how cannabis compounds work, in particular, and how they interact with drugs and dietary supplements. They also emphasize the need for an assessment of the risks these products pose to vulnerable populations, such as children, pregnant women, and the elderly. It is important that consumers have reliable risk and benefit information to make informed choices about initiating and continuing the use of these products.

Joining Raoul in submitting the comments are the attorneys general of Alabama, Alaska, California, Connecticut, Delaware, the District of Columbia, Guam, Hawaii, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Northern Mariana Islands, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, and Washington.

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July 16, 2019

Via Electronic Submission

Norman E. Sharpless, M.D., Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Docket No. FDA–2019–N–1482
Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds

Dear Commissioner Sharpless,

We, the undersigned State Attorneys General, submit this comment in response to the Food and Drug Administration's ("FDA") requests for comments on the safety, manufacturing, and sale of products containing cannabis or cannabis-derived compounds.[1] Importantly, in considering regulation of products that contain cannabis or cannabis-derived compounds, including cannabidiol (CBD), the FDA should continue to incorporate State Attorneys General feedback and ensure that states maintain a role as regulators in this emerging market.

As the primary enforcers of our respective states' consumer protection laws, we offer a unique perspective as to the new legalized market of certain cannabis and cannabis-derived compounds, including CBD products. We write to express our hope that the FDA continues to explore manufacturing, testing, and marketing best practices so that consumers are not at risk of misleading advertising or harm to their health from dangerous additives or undisclosed risks of use. Although products containing cannabis or cannabis-derived compounds may well offer real benefits to consumers, it is important that consumers have reliable risk and benefit information to make informed choices about initiating and continuing the use of these products. A crucial element of FDA regulation and oversight should be an on-going assessment of the potential risks or benefits of these products, particularly for specific populations such as pregnant women, adolescents and children, and the elderly. How these products interact with other dietary or pharmaceutical products should be included in this assessment. It is also important that companies not mislead consumers. Scientific and medical data from the FDA would assist in meaningful enforcement of advertising laws and regulations by the states.

Currently, companies are creating a myriad of cannabinoid products largely unburdened by any oversight or testing requirements. The inherent complexity of cannabinoids, combined with the danger of hazardous additives, raises

[1] *See* Request for Comments, Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds, 84 Fed. Reg. 12,969 (April 3, 2019).

serious public health concerns that absent some rules or regulations, unscrupulous companies will be able to distribute products that include illegal cannabinoid combinations or have dangerous additives.

Beyond these dangers, there is also the potential for products to be incorrectly or misleadingly labeled and packaged in ways that take advantage of consumers and puts them at risk. Although many operational companies making cannabis and CBD products appropriately test, package, and label their products, some do not. These products should be subject to testing and manufacturing guidelines in order to keep consumers appropriately informed and safe.

Ultimately, the responsibility for protecting consumers that use cannabinoids and CBD products cannot solely be left to the companies supplying products—that responsibility must include the FDA with meaningful partnerships with the states and State Attorneys General. We applaud the FDA's recent steps, including the formation of the CBD working group focused on exploring pathways for dietary supplements and food regulation, seeking to clarify code citations, regulating cosmetics, and researching existing science and developments.

We appreciate the FDA's willingness to listen to and consult with State Attorneys General on regulation of cannabinoids and CBD products. We hope that the FDA will continue to recognize the important role that states play in this emerging market, and that the FDA will incorporate the ongoing feedback that State Attorneys General provide.

Sincerely,

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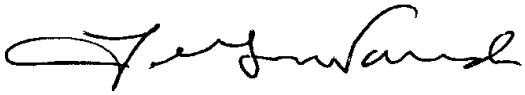

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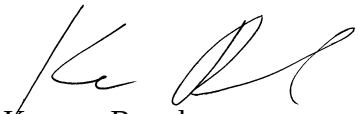

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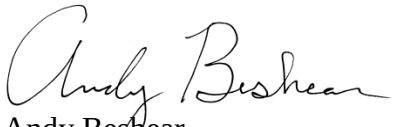

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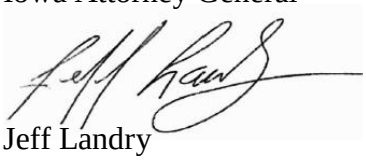

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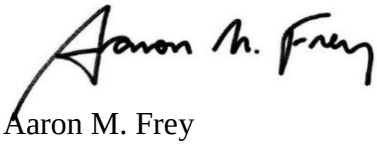

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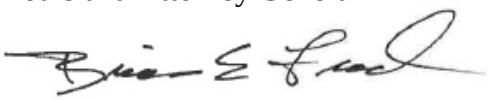

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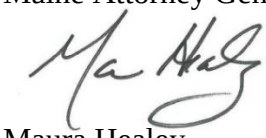

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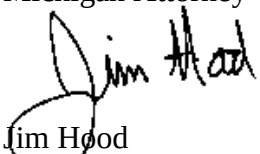

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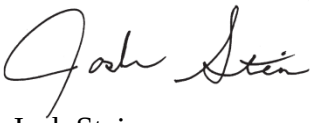

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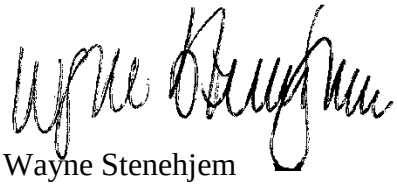

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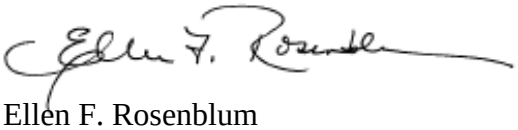

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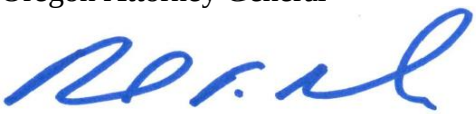

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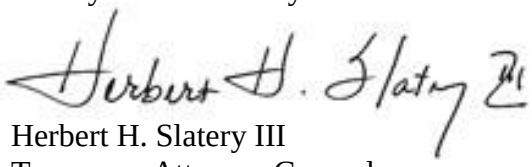

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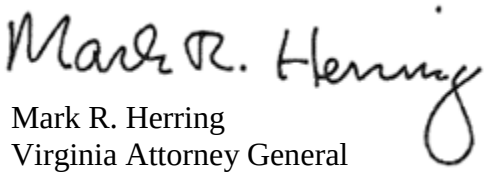

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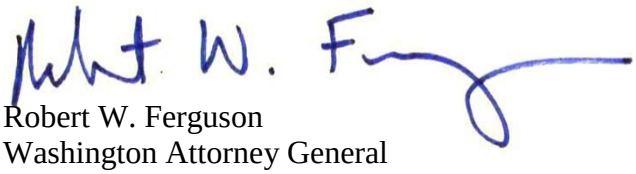

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