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January 11, 2021

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: FDA's Progress Under the SUPPORT Act

Dear Dr. Hahn,

We, the attorneys general of New Mexico, West Virginia, Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Guam, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, U.S. Virgin Islands, Virginia, Washington, and Wisconsin are writing to request an update on what actions the Food and Drug Administration ("FDA") has taken under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"), Pub. L. No. 115-271, to combat the opioid epidemic, and what actions are proposed for the near future. We have witnessed first-hand the devastation that the opioid epidemic has wrought on states in terms of lives lost and the costs it has imposed on our healthcare system and the broader economy. As the chief legal officers of our states, we are committed to using all tools at our disposal to combat this epidemic and to protect patients suffering from chronic pain or addiction, who are among the most vulnerable consumers in our society.

In the last few months, the top concern in America's healthcare industry has been mitigating the devastation caused by the COVID-19 outbreak. However, while COVID-19 deserves the attention it is receiving, the raging opioid epidemic must also be addressed. The loss and sense of despair brought by COVID-19 may even be refueling the opioid epidemic as people look to escape their fear and anxiety about the uncertain future that the virus has created. In fact, overdose rates have been growing by double-digits across the country since the pandemic started. *See, e.g., Covid-19 Impact on US National Overdose Crisis*, available at: http://odmap.org/Content/docs/news/2020/ODMAP-Report-June-2020.pdf (last visited Dec. 2, 2020).

We have been on the front lines to reduce opioid abuse and misuse and remain committed to this mission today. Each of our offices has seen the devastation that misused opioids have wrought on families and communities. We have pursued numerous paths and programs that promise to bring relief in this crisis. Included in these efforts was a letter to America's Health Insurance Plans asking its members to review and revise their payment and coverage policies to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain.

We also recognize the vital role the FDA plays in both ensuring the safety and efficacy of opioids and encouraging the availability of non-opioid, non-addictive alternatives for the treatment of pain. This role was highlighted in the SUPPORT Act which granted new authority to the FDA while also creating new requirements. We are most interested in four sections of the SUPPORT Act. More specifically, we are interested to know what the FDA has already accomplished with its new authority under those sections, and what it plans to accomplish in the future:

- **§3001 Clarifying the FDA Regulation of Non-Addictive Pain Products** – This section required the FDA to convene a public meeting covering the challenges in developing non-addictive medicine to treat acute or chronic pain and to issue at least one final guidance document to help address the challenges posed by developing non-addictive pain medications. Patient access to non-addictive pain therapies is critical to combating addiction and ensuring suitable pain relief for those in need, especially those in active recovery. What has the FDA done, what was learned from the meeting, and what does the FDA plan to do to address the challenges posed by developing non-addictive pain medications? How is the FDA clarifying procedures for expediting the review and approval of safe and effective non-addictive pain medications?

- **§3002 Evidence-Based Opioid Analgesic Prescribing Guidelines and Report** – This section requires that the FDA "develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain . . ." and issue a corresponding report. We know that the FDA has contracted with the National Academies of Science, Engineering, and Medicine to complete the guidelines and submitted a report to Congress on the implementation of §3002 last spring. This could be a valuable tool to prevent overprescribing of opioids that results in misuse and abuse of leftover medication. What advancements have been made to the guidelines and what are the FDA's plans to have them implemented?

- **§3032 Safety-Enhancing Packaging and Disposal Features** – This section allows the FDA to require that a drug be made available for dispensing in unit dose packaging, like blister packs, to mitigate serious risk of an adverse drug experience. It also allows the FDA to require a drug be dispensed "with a safe disposal packaging or safe disposal system for purposes of rendering drugs nonretrievable . . . if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available." Is the FDA considering requiring that any class of drugs or drugs for certain patients be dispensed in unit dose packaging or along with a safe disposal system? What information is being used to determine whether such a decision would be beneficial to patients and the public health?

- **§3041 Clarifying the FDA Postmarket Authorities** – This section required that the FDA issue guidance regarding circumstances in which it may "require postmarket studies or clinical trials to assess the potential reduction in effectiveness of a drug and how such reduction in effectiveness could result in a change to the benefits of the drug and the risks to the patient." Does the FDA foresee requiring any postmarket studies or clinical trials for any narcotics, considering the effects prescription opioids have had on countless families across the nation?

We welcome any other information you may wish to provide on any actions you have completed or have planned as they relate to the opioid epidemic. Because of the importance of this topic, we would appreciate a response within the next month. We thank you for the actions you have already taken to combat this crisis and appreciate you as a powerful partner in this fight.

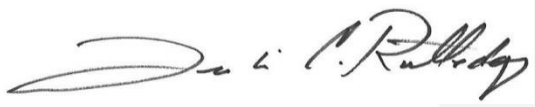
Sincerely,

Hector Balderas
New Mexico Attorney General

Patrick Morrisey
West Virginia Attorney General

Steve Marshall
Alabama Attorney General

Clyde "Ed" Sniffen, Jr.
Acting Alaska Attorney General



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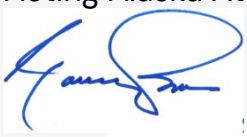

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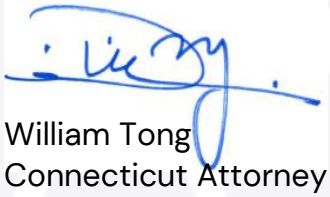

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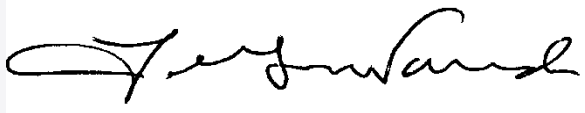

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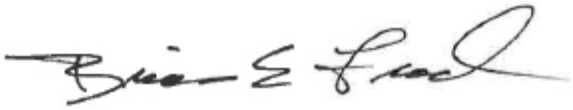

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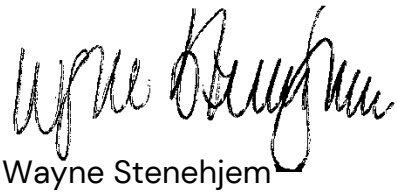

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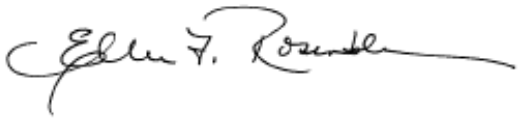

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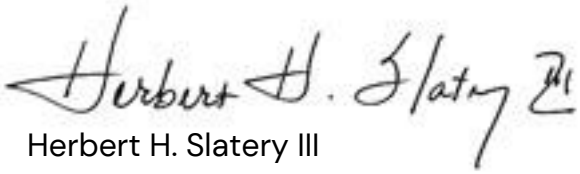

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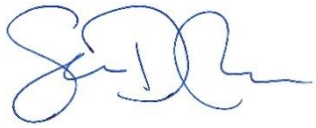

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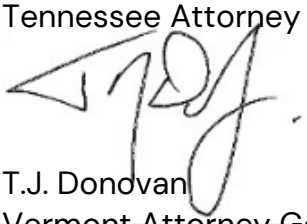

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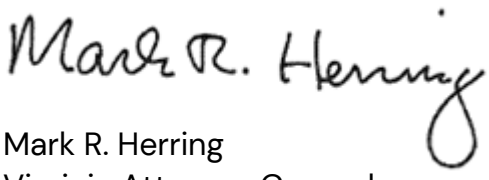

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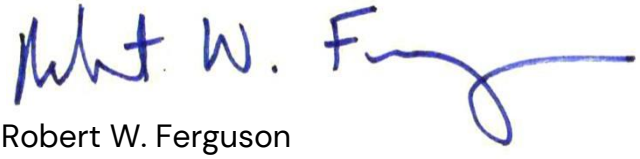

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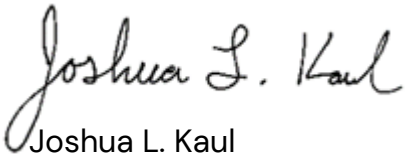

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