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April 1, 2019

Dr. Vanila Singh
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Avenue, S.W., Room 736E,
Attn: Alicia Richmond Scott, Task Force Designated Federal Officer
Washington, DC 20201

RE: Comments on the “[Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations](#)” Docket Number: HHS-OS-2018-0027

Dear Dr. Singh:

We, the undersigned Attorneys General, write to express our concerns with the Pain Management Best Practices Inter-Agency Task Force Draft Report (Draft Report). For many years, state attorneys general have been fighting the opioid crisis on numerous fronts, from protecting consumers against deceptive marketing of prescription opioids to closing pill mills. While this crisis continues, it is incomprehensible that officials would consider moving away from key components of the *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016* (CDC Guideline). The well-established risks associated with higher doses of opioids, prescriptions of longer duration, and concurrent prescriptions of opioids and benzodiazepines demand reasonable guidelines to inform appropriate decision-making.

Section 4 of the Draft Report proposes to rely solely on the judgment of providers regarding the dose and duration of opioid treatment. With annual overdose deaths in the tens of thousands, evidence-based recommendations, such as documentation and consultation, are necessary. Without reasonable dispute, widespread opioid prescribing causes immense harm.

In Washington, the Agency Medical Directors’ Group developed an evidence-based guideline that balances individual patient needs with the undeniable risks of high-dose opioids. Prior to prescribing high-dose opioids, providers are required to obtain a consultation from a trained pain specialist who agrees that a high dose is indicated and appropriate. In addition, providers must routinely monitor and document sustained improvement in function and quality of life and an absence of defined risk factors that increase risk for opioid use disorder and overdose. In contrast, the Draft Report emphasizes frequent monitoring of analgesic effectiveness, relegating function and quality of life measures to optional considerations.

The Draft Report should be revised to clearly state that there is no completely safe opioid dose, and that higher doses are particularly – and predictably –

risky. As noted in the Washington State Agency Medical Directors' Group *Interagency Guideline on Prescribing Opioids for Pain*, even with acute low dose opioids (1 – 36 mg/day morphine equivalent dose or MED), patients are at increased risk for developing opioid use disorder (OUD).ⁱ The likelihood of developing OUD ranges from a 3-fold increase for acute low dose opioids, to a 122-fold increase for chronic high dose opioids (≥ 120 mg/day MED) compared to patients who are not prescribed opioids.ⁱⁱ Overdose risk approximately doubles at doses between 20 and 49 mg/day MED, and increases nine-fold at doses of 100 mg/day MED or more.ⁱⁱⁱ Yet no dose is safe, as studies in Washington's workers' compensation and Medicaid programs have shown that nearly half of all overdose hospitalizations occur in patients who are on intermittent or lower dose opioids.^{iv,v}

Similarly, the Draft Report states that duration of opioid treatment for acute pain, including trauma and surgery, is best determined by providers without the need for guidelines to inform appropriate decision-making. Instead, the Draft Report should point providers to surgical guidelines issued since the CDC Guideline was published. For example, University of Michigan researchers have developed and made publicly available opioid prescribing recommendations for 25 common operations.^{vi} Implementing these guidelines has led to 35% to 66% reductions in opioid prescribing for several procedures with no impact on patients' pain, or their likelihood of requesting a refill.^{vii,viii} In Washington, the Bree Collaborative and the Agency Medical Directors' Group developed a post-operative prescribing guideline informed by more than 200 studies that have been published just in the past several years.^{ix}

The Draft Report also fails to acknowledge that longer duration prescriptions increase patients' risk for misuse and instead identifies patient characteristics as the drivers of misuse. A study of a million opioid-naïve surgical patients found that each additional week of opioid treatment was associated with a 20% increased risk for opioid misuse. A refill increased their total risk by 44%.^x Even shorter duration opioid prescriptions can increase risk for misuse, particularly for youth. For example, most dentists prescribe a median of 20 opioid pills for a tooth extraction^{xi}, many of which are left unused and available for misuse. Research has found that 16 to 25-year-olds who receive an opioid prescription for dental procedures are 14.5 times more likely than other youth to receive an opioid abuse diagnosis within a year.^{xii} Youth continue to face this risk, even though many studies have demonstrated that non-opioid analgesics are comparable or more effective for managing dental pain than opioids.^{xiii,xiv,xv} Rather than reiterating the importance of limiting exposure to opioids as much as possible, the Draft Report makes the baseless claim that opioids only have addictive properties in certain at-risk populations. While certain factors place individuals at higher risk for adverse events associated with opioid use, anyone can become dependent and misuse opioids, particularly if they are exposed to more opioids than necessary.

Moving away from the CDC Guideline at this critical time would undermine ongoing legislative initiatives, as well as refinements to standards of medical care. For example, the Montana Department of Justice is currently spearheading a bill through the Legislature that would bolster Montana's Prescription Drug Monitoring Program and limit opioid and benzodiazepine prescriptions to seven days. This policy change, like others throughout the country, relies on the CDC Guideline and has the broad support of the medical community, including the Montana Medical Association, Montana Hospital Association, and the Montana Pharmacy Association. As a number of studies have demonstrated, while most surgical patients use a fraction of their

prescriptions^{xvi}, fully 5% of adolescent patients become chronic opioids users.^{xvii} As Attorneys General of states with high rates of prescription drug abuse among our youth, policy makers and prescribers must be encouraged to continue to pursue laws and practices that reduce the high volume of opioids in our communities.

Finally, the Draft Report must be revised regarding co-prescribing of opioids and benzodiazepines. According to the National Institute on Drug Abuse, more than 30 percent of overdoses involving opioids also involve benzodiazepines. The overdose death rate among patients receiving both types of medications is up to 10 times higher than among those only receiving opioids.^{xviii} The CDC Guideline appropriately warns against co-prescribing, yet does not prohibit it outright. Instead, providers are advised to offer naloxone, re-evaluate patients more frequently, and refer patients to pain and/or behavioral health specialists.

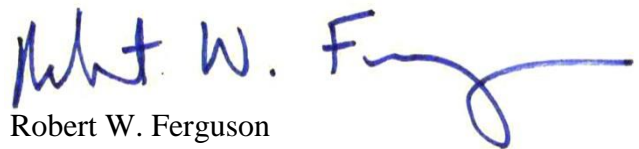
The Draft Report provides no justification for moving away from the CDC recommendation that clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. If the Draft Report aims to bring new research to providers' attention, it should point out that concurrent opioid and benzodiazepine prescriptions are already all too common – and providers may not even be aware the extent to which their own patient panel is affected. Recent research found that more than a quarter of Medicare patients prescribed opioids also fill prescriptions for benzodiazepines.^{xix} This study found the risk of concurrent opioid and benzodiazepine use rose with the number of clinicians prescribing medications to the same patient, pointing to the need for increased communication between providers and reinforcing the value of Prescription Drug Monitoring Programs.

Since the CDC Guideline was issued, the evidence has continued to mount that opioids achieve limited pain relief for chronic noncancer pain^{xx} and are often no better than other options for treating acute pain.^{xxi} As attorneys general we have witnessed the devastating effect of unfettered opioid manufacturing, distribution and prescribing on our public health, social services and criminal justice systems. The well-established risks associated with higher doses of opioids, prescriptions of longer duration, and concurrent prescriptions of opioids and benzodiazepines demand continued constraints. As a matter of public safety, there is simply no justification to move away from the CDC Guideline to encourage more liberal use of an ineffective treatment that causes nearly 50,000 deaths annually.

Sincerely,




Tim Fox
Montana Attorney General



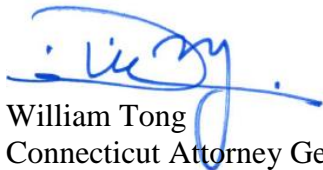
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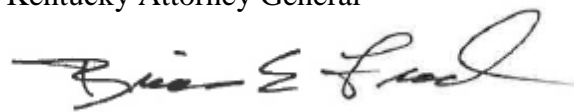
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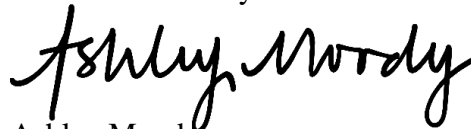
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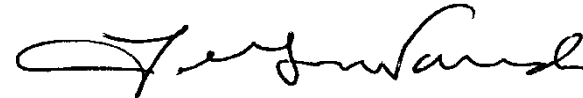
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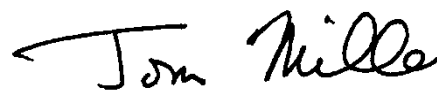
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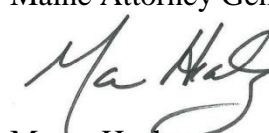
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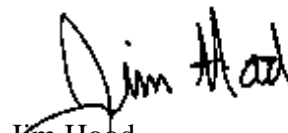
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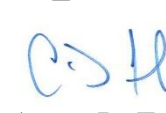
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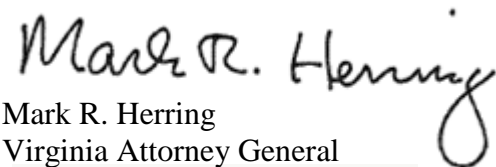
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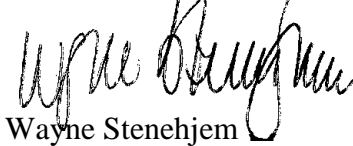
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- ⁱ Washington State Agency Medical Directors' Group. (2015). *Interagency Guideline on Prescribing Opioids for Pain*. Retrieved from: <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>
- ⁱⁱ Edlund MJ, Martin BC, Russo JE, DeVries A, Braden JB, Sullivan MD. (2014). The role of opioid prescription in incident opioid abuse and dependence among individuals with chronic noncancer pain: the role of opioid prescription. *Clinical Journal of Pain*;30: 557-64.
- ⁱⁱⁱ Supra note 1.
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- ^v Fulton-Kehoe D, Garg RK, Turner JA, et al. (2013). Opioid poisonings and opioid adverse effects in workers in Washington state. *American Journal of Industrial Medicine*; 56:1452-62.
- ^{vi} The recommendations are available at: <https://opioidprescribing.info/>
- ^{vii} Howard R, Waljee J, Brummett C, Englesbe M, Lee J. (2018). Reduction in opioid prescribing through evidence-based prescribing guidelines. *JAMA Surgery*, 153:285-287.
- ^{viii} Howard R, Alameddine M, Klueh M, Englesbe M, Brummett C, Waljee J, Lee J. (2018). Spillover Effect of Evidence-Based Postoperative Opioid Prescribing. *Journal of the American College of Surgeons*, 227: 374-381.
- ^{ix} The Guideline is available at: www.breecollaborative.org/wp-content/uploads/Final-Supplemental-Bree-AMDG-Postop-pain-091318-wcover.pdf
- ^x Brat GA, Agniel D, Bearn A, et al. (2018). Postsurgical prescriptions for opioid naïve patients and association with overdose and misuse: retrospective cohort study. *BMJ*, 360: j5790. doi: <https://doi.org/10.1136/bmj.j5790>.
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- ^{xiii} Dionne RA, Gordon SM, Moore PA (2016). Prescribing Opioid Analgesics for Acute Dental Pain: Time to Change Clinical Practices in Response to Evidence and Misperceptions. *Compendium of Continuing Education in Dentistry*, 37:372-378.
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