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Acting Commissioner Janet Woodcock, MD
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Docket Number: FDA-2021-N-0951-0001 FDA Workshop on Opioid Prescriber Education

Dear Dr. Woodcock:

On behalf of its 40,000 members, the Academy of General Dentistry (AGD) appreciates the opportunity to provide comments on potential federal actions for additional opioid Risk Evaluation and Mitigation Strategies (REMS). As an educational organization, the AGD offers general dentists, and other dental health care providers, with quality continuing education (CE) on a variety of clinical and practice management topics, including best practices for prescribing opioids.

On October 13-14, 2021, the FDA partnered with the Duke-Margolis Center for Health Policy to explore the concept of implementing a mandatory CE requirement for prescribers of opioid medications.¹ The AGD strongly recommends against this action and maintains that federal mandatory CE on opioids is duplicative and offers the American public no real protections from the multi-factorial issues of opioid addiction, overuse and overdose.

The AGD asserts that multiple federal agencies must work in tandem to protect our citizenry from drug addiction, abuse and poisonings. Therefore, our comments are directed to agencies beyond the FDA and we encourage you to share this letter with the appropriate personnel in other agencies under the purview of the Department of Health and Human Services (HHS) as well as with staff in federal law enforcement agencies, such as the Drug Enforcement Agency (DEA).

Mandatory Continuing Education (CE) in States

The majority of states in the U.S. require continuing dental education on opioid prescribing. Similarly, over 40 states in the nation require continuing medical education on opioid prescribing as part of a requirement for a physician's licensure. As most clinicians are required to complete opioid pain control CE to maintain their licenses, we are unsure what would be gained by a federal mandate for CE on opioid prescribing.

The FDA is proposing a generic, non-specific solution to a specific problem. As was discussed during the FDA-Duke Margolis workshop, clinicians often learn from sharing information with each other during grand rounds and other venues.

Prescribing Guidelines and State Limitations

Dentists use prescribing guidelines from the Center for Opioid Research and Education other sources.^{2,3} Pain from most dental procedures can be controlled with a combination of Acetaminophen

¹ FDA Public Workshop on Opioid Prescriber Education. October 13-14, 2021 [FDA Public Workshop on Opioid Prescriber Education \(duke.edu\)](https://www.fda.gov/oc/2021/10/13-fda-public-workshop-on-opioid-prescriber-education)

² Center for Opioid Research and Education. <https://www.solvethecrisis.org/dental-guidelines>

³ Evidence-Based Clinical Practice Guideline for the Management of Acute Dental Pain. American Dental Association, November 2021. [acutepaincpreccs_2021nov19_forpubliccomment.pdf \(ada.org\)](https://www.ada.org/~/media/ADA/Research/2021/11/2021nov19_forpubliccomment.pdf)

and Ibuprofen, thereby obviating the need for opioids. Health care associations including the American College of Surgeons (ACS) distributed guidelines on recommended limitations for procedures and length of opioid prescribing.^{4,5}

The vast majority of practitioners adhere to best practices. Additional educational requirements are likely to be met with resistance as participants of the FDA-Duke workshop stated that mandates are never attractive and can prove to be counterproductive.

Additionally, at least 33 states impose strict limitations or impose guidelines on the number of opioids a clinician can prescribe for a specific surgical procedure.⁶ In fact, changes to opioid prescribing behaviors of clinicians and restrictions at the state level of prescription drug monitoring program (PDMP) access, mandatory PDMPs, pain clinic laws, prescription limiting laws, naloxone access laws, and Good Samaritan laws were associated with a decrease in the misuse of prescription opioids. However, these interventions are presumed to have led to the unintended consequence of increasing the use of alternative illicit substances and higher mortalities.⁷

Changing Behavior of Prescribers

Participants in the FDA-Duke workshop were not convinced that a one-size-fits-all approach to opioid prescribing CE would provide the desired effect to change behaviors. It is unlikely that single educational intervention will change the behavior of prescribers of opioids. Certain specialists such as those providing palliative care prescribe large quantities of opioids for end-of-life care.

Illicit Drug Trade

According to the National Center for Health Statistics (NCHS), drug overdose deaths surpassed 100,000 in the United States between April 2020 and April 2021.⁸ Fentanyl is driving the majority of these deaths, associated with at least 60% of the fatal overdoses – a 50% increase in a single year, according to Nora Volkow, MD, Director of the National Institute on Drug Abuse.⁹

Drug Enforcement Agency (DEA)

The *Ensuring Patient Access and Effective Drug Enforcement* was signed into law (Public Law 114-145) on April 9, 2016.¹⁰ Subsequent to the passage of the law, officials at the DEA find that it is nearly impossible to freeze suspicious shipments of narcotics that do not pose an imminent threat of death or

⁴ [Guideline for reducing opioid use post-surgery leads to high pain management satisfaction \(facs.org\)](#)

⁵ Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus. Aug. 14, 2018. Overton, et.al. J Am Coll Surg. [Opioid-Prescribing Guidelines for Common Surgical Procedures: An Expert Panel Consensus \(nih.gov\)](#)

⁶ Prescribing Policies: States Confront Opioid Overdose Epidemic. National Conference of State Legislators. June 30, 2019. [Prescribing Policies: States Confront Opioid Overdose Epidemic \(ncsl.org\)](#)

⁷ Systematic Evaluation of State Policy Interventions Targeting the US Opioid Epidemic, 2007-2018. Lee. et al Feb. 12, 2021. JAMA Open Network; 4(2):e2036687 [Systematic Evaluation of State Policy Interventions Targeting the US Opioid Epidemic, 2007-2018 | Psychiatry and Behavioral Health | JAMA Network Open | JAMA Network](#)

⁸ National Center for Health Statistics. 12-month ending Provisional Counts and Percent Change of Drug Overdose Deaths. [Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data \(cdc.gov\)](#)

⁹ Melody Schreiber. It's Devastating: How Fentanyl is Unfolding as One of America's Greatest Tragedies. The Guardian. Nov. 22, 2021.

¹⁰ Ensuring Patient Access and Effective Drug Enforcement Public Law 114-145. [Text - S.483 - 114th Congress \(2015-2016\): Ensuring Patient Access and Effective Drug Enforcement Act of 2016 | Congress.gov | Library of Congress](#)

grave harm to users. In the law, the use of the word “imminent” has aided and abetted the trafficking of opioids and other substances within U.S. borders. The restrictive language helps legal and illegal drug manufacturers and distributors to the detriment of our citizens. The AGD encourages a legislative remedy to rectify this unfortunate choice of language as soon as it can reasonably be accomplished. Law enforcement must be able to immediately halt the distribution of suspicious substances that may cause harm to our citizens and visitors.

On September 27, 2021, the DEA issued a Public Safety Alert warning Americans of the alarming increase in the lethality and availability of fake prescription pills containing fentanyl and methamphetamine.^{11, 12} This was the first alert sent to the public in six years to raise public awareness that “pills are mass-produced by criminal drug networks in labs, deceptively marketed as legitimate prescription pills, and are killing unsuspecting Americans at an unprecedented rate.”

Conclusion

The AGD understands that the FDA will hold a public meeting to assess sentiment for a mandatory REMS for prescription opioids. We stand ready to partner with you on this issue and invite you to contact Daniel J. Buksa, JD, Associate Executive Director, Public Affairs, by phone at (312) 440-4328 or via email at daniel.buksa@agd.org if you have questions or would like to discuss our comments in greater detail.

Sincerely,



Gerald J. Botko, MS, DMD, MAGD
AGD President



Joseph Battaglia, MS, DMD
AGD Chair, Dental Practice Council



Myron (Mike) Bromberg, DDS
AGD Chair, Legislative & Governmental
Affairs Council
AGD Congressional Liaison

¹¹ [DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth](#)

¹² 2021 Update: Illegal Pill Presses: An Overlooked Threat to American Patients. National Association of Drug Diversion Investigators and the Partnership for Safe Medicines. April 2021. [2021-Update-PillPress-Report-SECURE-2.pdf \(safemedicines.org\)](#)