American Medical Association discussion concerning mandatory REMS as a proposal for addressing the nation's drug overdose epidemic

FDA-Duke Margolis Public Workshop on Opioid Prescriber Education
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On behalf of the American Medical Association (AMA), thank you for the opportunity to provide comments on the issues under consideration at this hearing. My name is Dr. Bobby Mukkamala. I'm a practicing otolaryngologist from Flint, Michigan and Chair of the AMA Board of Trustees. I'm also Chair of the AMA Substance Use and Pain Care Task Force.

It bears repeating that the nation's overdose epidemic has become worse. We know that the data show how the epidemic has changed from one where the majority of death was related to heroin and prescription opioids. And that starting in about 2015-2016, mortality related to illicitly manufactured fentanyl, fentanyl analogs, methamphetamine and cocaine became the primary drivers. Mortality related to heroin and prescription opioids remains far too high. Millions of Americans, however, still do not receive treatment for a substance use disorder (SUD), mental illness or pain.

We also still have a major nonmedical use problem. The National Survey on Drug Use and Health has reported for years that 60-70 percent of nonmedical use of opioid analgesics is due to stolen or given-away pills. The AMA does not believe that a mandatory opioid prescribing REMS will reduce mortality, diversion or improve patient care. The mortality is not being driven by prescriptions. Thus we need to look at the true problem: illicit use and SUD

The most common policy interventions across the country have been mandates to restrict opioid prescriptions, mandates to use prescription drug monitoring programs, and mandates to take a few hours of continuing medical education on pain, prescribing, substance use disorders and related areas. Mandates for continuing education – as the FSMB can tell you – range from one or two hours per licensing cycle – to a one-time 12-hour requirement in California.

In Michigan, the 2018 CME mandate says that every three years, I have to take three hours—out of 150—in pain and symptom management. I prescribed very few opioids before the mandate, and I prescribe about the same after. CME mandate debates don't remove administrative barriers to treatment for mental illness or substance use disorders or allow us to focus on increasing equitable, affordable options for patients with pain. Data from CDC, NIDA and other sources show no correlation between CME mandates and reduced mortality.

For example, illicit fentanyl began to sharply rise in Michigan in 2014-2015. By 2016, mortality related to prescription opioids began to plateau, but heroin-related mortality continued to increase. Around the same time, illicit fentanyl became the main driver of drug-related mortality, and is now more than triple either heroin or prescription opioids. Cocaine-related mortality has always been higher than prescription opioids.

Between 2011 and 2020, opioid prescriptions decreased by more than 55 percent in Michigan—well above the national average. If you look at nearly every other state, it's the same story. Reductions in

opioid analgesics plus CME mandates have not equaled reductions in mortality or improved outcomes for patients with pain. Despite physicians' efforts, the numbers are getting worse.

Consider a few national data: Between 2011-2020, opioid prescriptions decreased by 44.4 percent; during the same time period the MME from those prescriptions decreased by more than 55 percent. PDMP use nationally increased from 61.5 million queries in 2014 to more than 910 million in 2020. And naloxone prescriptions have seen an increase from about 40,000 prescriptions per year in 2016 to well over one million in 2019.

These positive trends, however, have not reversed the trajectory of the epidemic. To be meaningful, education must be specific to a physician's clinical practice and patient population. The AMA, through our flagship journal JAMA, our Education Hub, and our Task Force, provides access to hundreds of educational resources that are specialty-specific. We support the Prescribers Clinical Support System and FORE – the Foundation for Opioid Response Efforts as two additional education providers with high-quality offerings.

Physicians continue to educate themselves through many avenues. Education provided by medical societies has increased from courses and materials being accessed about 120,000 times per year in 2015-2016 to courses and materials being accessed several million times each year. As the data I've shown make clear, we do not have any reason to think that a lack of sufficient education about prescription opioid analgesics is the reason that the drug overdose epidemic has persisted and gotten much worse.

Other barriers are having a significantly greater impact. Health insurance prior authorization requirements, narrow networks and coverage denials are preventing patients from getting treatment for substance use disorders and comprehensive, individualized treatment for pain. Teaching me the right thing to do is not helpful when I simply cannot get the right thing done due to these barriers. By further stigmatizing opioids and patients who rely on them, a mandatory REMS program is likely to exacerbate these problems.

Let's remember that opioid prescribing reductions began in 2011-2012—and continue in every state whether there is an opioid prescribing restriction or CME mandate. The AMA Task Force in 2014-2015 recommended that if opioid analgesics were clinically indicated, prescribe the lowest effective dose for the shortest clinical duration and do not increase that dose or duration unless the expected benefits outweighed the known risks.

Physicians embraced that approach, as have many health systems and private practices. Through internal review procedures and academic detailing programs, physicians and health systems review prescribing patterns in a non-punitive way to learn why some are so-called higher prescribers—or low prescribers. The discussions for Ob, general surgery, neurosurgery, trauma are all different – as we would expect – because the circumstances are different. A mandatory REMS would not be able to address important clinical differences.

Rather than a mandatory REMS, there is a great need to support GME programs to hire core faculty in pain medicine and addiction medicine and psychiatry. We applaud FDA's approval of a higher dose naloxone formulation. It doesn't remove the need for community-based, affordable naloxone, but it is a great step forward. The AMA strongly supports FDA's efforts to make it easier for naloxone manufacturers to submit OTC applications—we continue to urge those manufacturers to do so.

We urge FDA to review labeling for buprenorphine to account for the need for higher doses in response to illicit fentanyl. The current labeling causes health insurance plans to delay and deny higher doses even when addiction medicine physicians report efficacy at higher doses.

We urge FDA to support efforts for medications to treat substance use disorders related to methamphetamine and cocaine. We support efforts to remove arbitrary thresholds in the 2016 CDC opioid prescribing guideline. And finally, the AMA stands ready to work with FDA on education efforts targeted at employers to help destigmatize medications for pain and for substance use disorders. We are doing that now with DEA, and we would gladly support partnering with FDA to increase access to evidence-based care for patients with pain or a substance use disorder.

Thank you.