

United States Senate

WASHINGTON, DC 20510

October 18, 2021

U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Docket No. FDA-2021-N-0951 for “Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Opioid Crisis.”

To Whom It May Concern:

As part of the Food and Drug Administration’s (FDA) ongoing efforts to combat the worsening opioid epidemic, we write to express our support for the agency’s renewed consideration of mandatory prescriber education for opioids, including as part of a Risk Evaluation and Mitigation Strategy (REMS).

Last year was the deadliest year for drug overdoses in America’s history. We know that the opioid epidemic was fueled by the sheer number of opioid painkillers that are manufactured, prescribed, and dispensed in the United States—with four out of five new heroin users starting their addiction with prescription opioids. While opioid dispensing has decreased in recent years, there were still more than 153 million opioid prescriptions filled in 2019—enough for nearly two-thirds of adults to have a bottle of painkillers. As recently as 2018, hydrocodone-based opioids were the single most commonly prescribed medication in 10 states.

We have urged FDA for years to apply its enhanced safety framework as a mandatory form of education for opioid prescribers. The FDA’s Drug Safety and Risk Management (DSaRM) Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) have also voted against voluntary education and training for opioid prescribers, with many members expressing support for a mandatory program. While we acknowledge and commend the FDA for important steps it has undertaken in recent years to extend its REMS program to immediate release opioids and remove certain products from the market, we believe the current regulatory oversight for opioid prescribing fails to meet the ongoing risks posed to public health.

To date, the FDA’s REMS has only required that sponsors of opioids make an education program available to prescribers. This hands-off approach has been insufficient to prevent inappropriate prescribing, misuse, and abuse of opioids. Alarming, only 354,949 prescribers completed the REMS opioid continuing education courses over the past 9 years—compared to approximately 1 million licensed opioid prescribers in a given year. It makes no sense that health professionals have needed to undergo hours of mandatory training to prescribe buprenorphine or other FDA-approved treatments for opioid use disorder, when there is no mandatory training required for the very opioids that caused such addiction in the first place. What’s clear is that FDA’s voluntary approach to date does not meet the challenge.

After years of deceptive promotion from the pharmaceutical industry that mischaracterized the risks and benefits of opioids, it is essential that today's prescribers have the most recent understanding about appropriate prescribing practices, pain management, and prevention and treatment of addiction. Thankfully, in recent years, new research and data—including from the Centers for Disease Control and Prevention (CDC) and Agency for Healthcare Research and Quality (AHRQ)—have underscored improved guidelines and responsible opioid prescribing considerations. We believe it is essential that all opioid prescribers across America have this important and renewed educational understanding, and as part of a move to mandatory opioid prescriber education, we urge FDA to update its REMS curriculum and educational content to reflect the latest understandings and evidence from CDC and AHRQ.

Continuing a system of voluntary prescriber education for addictive opioids would ignore the reality of: the ongoing promotion by pharmaceutical sales representatives of prescription painkillers; how individuals get hooked on heroin and fentanyl; and the shortcomings of the current preventive regulatory framework. We appreciate the FDA's actions to reconsider its REMS program to make opioid prescriber education mandatory, and we urge the FDA to finally implement this public health policy.

Sincerely,



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator



Joe Manchin III
United States Senator