



## The EFFECTIVE Act

*Reps. David Trone (D-MD) and Dan Meuser (R-PA)*

### The Problem

In 2021, over 107,000 Americans died from drug overdoses — more than twice the number of U.S. traffic fatalities or gun violence deaths during that period.<sup>i</sup> The opioid epidemic has continued to take the lives of loved ones of all ages, but tragically, drug overdoses have become the leading cause of death for 18 to 45-year-olds in the U.S.<sup>ii</sup> This problem originated in the 1990s when pharmaceutical companies reassured the medical community that patients would not become addicted to opioid pain relievers, and healthcare providers subsequently prescribed them at greater rates.<sup>iii</sup>

In February 2023, the Food and Drug Administration (FDA) shared a report commissioned to review FDA's opioid-related activities.<sup>iv</sup> In the report's release, the FDA notes that the agency currently "lacks the statutory authority to require that drug developers seeking approval for the marketing of new opioid products demonstrate that their products offer material safety advantages (such as a reduction in [misuse] potential or a reduction in respiratory depression) over existing approved opioids. By enabling the FDA to refuse to approve new opioid analgesics that do not offer material safety advantages over already-approved opioids there is potential to, over time, improve the safety of opioid analgesics available to treat severe acute and chronic pain or drive research towards non-opioid alternatives to relieve pain."<sup>v</sup>

### **What does the *Ensuring the FDA Fully Examines Clinical Trial Impact and Vitalness Before Endorsement (EFFECTIVE) Act* do?**

The EFFECTIVE Act gives the FDA authority to deny a new drug application for an opioid analgesic if the drug is not more clinically effective or safer than any commercially available drug. The bill applies to applications for new drugs and would not impact the approval of generics. This legislation would give the FDA more power to review the public health impact of every new opioid approval, as well as incentivize development of safer and more effective drugs.

### **Support for the EFFECTIVE Act**

Companion led by Sens. Joe Manchin (D-WV) and Mike Braun (R-IN)

Endorsing organizations: Community Anti-Drug Coalitions of America (CADCA), National Association of Addiction Treatment Providers, SAFE Project



i <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

ii [https://www.yahoo.com/how/fentanyl-leading-cause-death-americans-100158708.html?guccounter=1&guce\\_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce\\_referrer\\_sig=AQAAADV EpTTxRYnnW15Erujj2E8dLTOW9ruhUTT69VWUS7VyYoi7M10rAdeRoPtG\\_A54RGx-YGWzVUIr5YWuNfNUbXM2zxmhL2Amj6JXEXdT5IAR0maJ6leeVz0CeW6zaprCxq0sjzZtI7K1CeZLwGgJztYD7qSmIEvHKbKIhbk34](https://www.yahoo.com/how/fentanyl-leading-cause-death-americans-100158708.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAADV EpTTxRYnnW15Erujj2E8dLTOW9ruhUTT69VWUS7VyYoi7M10rAdeRoPtG_A54RGx-YGWzVUIr5YWuNfNUbXM2zxmhL2Amj6JXEXdT5IAR0maJ6leeVz0CeW6zaprCxq0sjzZtI7K1CeZLwGgJztYD7qSmIEvHKbKIhbk34)

iii <https://www.hhs.gov/opioids/about-the-epidemic/index.html>

iv <https://www.fda.gov/media/165238/download>

v <https://www.fda.gov/news-events/press-announcements/fda-advances-additional-activities-prevent-drug-overdoses-and-reduce-death>